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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Enforcement Committee Report

John Jones, Chair
Stan Goldenberg
Bill Powers

Report of September 17, 2003

NO ACTION

Importation of Drugs from Canada

Current federal law allows for the reimportation of drugs if the Secretary of Health and Human Services (HHS) certifies the safety of the system. The Secretary of HHS has never certified the safety of a reimportation system.

Prescription drugs are expensive. The US is the last industrialized county without price controls on drugs. As such, most international drug companies develop and introduce drugs for the US first in order to gain the most favorable return on their investment.

Because prescription prices are high in the US and less costly in the rest of the world (which is price controlled), there is a great incentive by American consumers to obtain necessary drugs from other nations. Due to similarities of regulatory systems and common language, many feel safe about importing prescription drugs from Canada and the numbers are rapidly growing. Importation from Mexico and other countries via cross border forays and the Internet are also an issue but the Canadian system is considered to be safer and is therefore preferred.

For Americans, the savings on a prescription via Canada ranges from 20-80%. Although obtaining prescriptions from Canada is illegal, the federal Food and Drug Administration (FDA) and US Customs have expressed that they will not intercept shipments or prosecute individual Americans seeking to buy their prescriptions this way.

As a result, the FDA and state Boards of Pharmacy are confronted with new entities that are "store fronts" for Canadian pharmacies. Theses entities act as brokers for prescriptions between the consumer and the Canadian pharmacies. They locate near senior centers and communities and aggressively advertise. These storefronts require no training, no pharmacy license and little expense to set up their business. There is question as to whether or not they are subjected to Board of Pharmacy regulation because they do not operate as a traditional pharmacy.

The Enforcement Committee and the Board of Pharmacy have been discussing importation of prescription drugs from Canada through these storefront operations at each meeting since April. Senator Alarcon requested an Attorney General Opinion, to which the FDA provided a response

as to the federal requirements. The board has produced a consumer booklet on dealing with the high cost of buying prescriptions. It describes discount programs, use of generics, manufacturer assistance programs and deals with the risks of shopping over the Internet or acquiring drugs from other countries. There has been action by other state Boards of Pharmacy and the FDA against these storefront operations. This board has stated its concern both with patient safety and access to affordable prescriptions. There is concern with the risks inherent to consumers using a system not regulated in the US.

The board will continue its discussion regarding the importation of drugs from Canada and will take testimony from the public. The board has not received any consumer complaints; however, it has received numerous complaints from businesses and licensees against these storefront entities for unfair business practices and using a pharmacy-related sign.
(Attachment A)

Prohibition of Pharmacy-Related Signs on Non-Pharmacy Businesses or Buildings

The Enforcement Committee reviewed Business and Professions Code section 4343 in response to the Governor's directive to evaluate the board's mandates to determine if they are necessary in light of the state's fiscal condition. The committee concluded that the law did serve a useful purpose and should be retained.

Business and Professions Code section 4343 establishes a prohibition on the use of signage that includes words such as "pharmacy," "drugstore," "apothecary," or words of similar import unless the premise is a licensed pharmacy. Although the board has never received a consumer complaint regarding the use of pharmacy-related signage, the law is enforced when the use of such signage may be misleading to the public. The board has been requested to enforce this provision against storefront facilities that assist consumers in obtaining prescription medications from Canada. It was discussed that the use of pharmacy-related signage in this instance is not confusing to the consumer.

It was noted that the origin of this prohibition was in 1905 that established a general regulation of pharmacists. It brought existing "pharmacies" by whatever name, under the board's regulatory authority. It was an inclusive statute designed to assert the board's jurisdiction over existing businesses. While over the years the law has been changed, the intent of this section has remained constant.

It was also discussed that the board has very little enforcement options because it is non-licensed entities that violate this section of law. Usually the only option is refer the matter to the local district attorney to file a criminal complaint. **(Attachment B)**

Proposed Citation and Fine Statute for Wholesale Violations and Proposed Regulations Regarding Wholesale Transactions

At the July Enforcement Committee meeting, Supervising Inspector Judi Nurse gave an overview regarding bid contract diversion in California. Pharmacies purchase "bid contract"

drugs at special prices and then through a common ownership transfer the drugs to its wholesale facility to be resold to other wholesalers. Often times, there is no record for these drug transactions. The drugs are resold several times through many wholesalers and many states in largely undocumented transactions that are impossible to trace. This "gray market" system has allowed for counterfeiting which is the dilution, mislabeling or adulteration of drugs. The unscrupulous companies can turn one shipment of injectable medications into many by watering down the drugs and reproducing the packaging. **(Attachment C)**

The issue of bid contract diversion and the proliferation of counterfeit drugs have caused the committee to propose regulations to ensure the integrity of California's drug distribution system. The committee discussed the regulation proposal at its last meeting and comments were made that the regulation would impede legitimate business transactions and modifications were suggested. It was also stated that the federal PDMA allows for intra-company sales, which may be contrary to the proposal. While the board had been using Nevada as its model for the regulatory framework, it was suggested that the committee might want to review the Florida legislation. This new legislation identifies a list of drugs that requires due diligence in authenticating prior transactions on pedigrees.

Chair John Jones requested interested parties to submit proposed language to address the concerns that were discussed; however, none were provided. Therefore, staff prepared a new regulatory proposal to address wholesale and pharmacy transactions. In addition, a legislative proposal was prepared for citation and fine authority for wholesale violations. It was explained that the legislative proposal was intended to seek monetary sanctions for economic motivations for law violations. While the board can pursue cases administratively for these same violations, usually by the time any formal action is pursued, the wholesaler permit is cancelled and the board has no authority over the non-licensed owners.

There was considerable discussion regarding the burden that the proposed regulations would place on the wholesaler. Currently, drugs are not tracked by lot numbers and it would be unreasonable to limit the sale or transfer of a drug to three times prior to being furnished to the final consumer. It was unclear as to the magnitude of the problem and the committee asked staff to provide documentation at its next meeting in December before making a recommendation to the board. **(Attachment D)**

Medical Board of California (MBC)/Board of Pharmacy Joint Task Force on Prescriber Dispensing

The Medical Board of California (MBC) and the Board of Pharmacy held a joint task force meeting on the issue of prescriber dispensing. Board President John Jones and Stan Goldenberg represented the board. The meeting was held on May 27, 2003, and the task force reached consensus on the following: (1) Under current law, an individual prescriber can own his/her own prescription stock and dispense to his or her own patients as specified and such practice should be allowed to continue with the goal of strengthening and educating prescribers regarding the record keeping requirements; (2) Allow a medical group to dispense prescription medications pursuant to a special permit issued by the Board of Pharmacy and specified conditions that

require one physician from the medical group to be responsible and accountable for the security of the prescription medications, record keeping requirements, and a consultant pharmacist reviews the dispensing process; (3) Establish the authority for a pharmacy to place an automated dispensing device in a prescriber's office; and (4) Provide for joint oversight by the appropriate licensing agencies.

The task force agreed that staff from the two boards would work together to draft language for each board to consider as a possible joint legislative proposal for 2004. Draft language was developed and the Medical Board task force members provided comments on the draft. The language was reworked to address their comments. The proposal would require a special clinic licensure for these group practices, which would have a fiscal impact to the board.

The interested parties expressed concern that they had just received the proposed language and did not have sufficient time to review it and provide comment. There was also discussion that consensus was not reached on this issue contrary to the statement made by the task force. The Enforcement Committee agreed to discuss this issue at its December meeting so that the interested parties had sufficient time to review the proposal. **(Attachment E)**

Implementation of Enforcement Provisions from SB 361

SB 361 (Figueroa) is the legislative vehicle for the Board of Pharmacy sunset extension and contains statutory recommendations approved by the Joint Legislative Sunset Review Committee. The following compliance provisions were recommendations from the board and included in SB 361. They will be added to California Pharmacy Law effective January 1, 2004.

- **Section 4083 – Order of Correction**

Would allow an inspector to issue an order of correction to a licensee directing the licensee to comply with the Pharmacy Law within 30 days by submitting a corrective action plan to the inspector or the licensee can contest the order of correction to the executive office for an office conference. If an office conference is not requested, compliance with the order does not constitute an admission of the violation noted in the order of correction and the order of correction is not considered a public record for purposes of disclosure. The licensee must maintain on the pharmacy premises a copy of the order of correction and corrective action plan for at least three years from the date the order was issued.

- **Section 4315 – Letter of Admonishment**

Would authorize the executive officer to issue a letter of admonishment to a licensee for failure to comply with Pharmacy law, directing the licensee to come into compliance within 30 days by submitting a corrective action plan to the executive officer documenting compliance, or the licensee can contest the letter of admonishment to the executive office for an office conference. If an office conference is not requested, compliance with the letter of admonishment does not constitute an admission of the violation noted in the letter of admonishment. The licensee must maintain on the pharmacy premises a copy of the letter of admonishment and corrective action plan for at least three years from the date the letter was issued. The letter of admonishment would be considered a public record for purposes of disclosure.

- **Section 4314 – Issuance of Citations**

Would allow the board to issue an order of abatement that would require a person or entity to whom a citation has been issued to demonstrate how future compliance with the Pharmacy Law will be accomplished and provides that such demonstration may include, but not be limited to, submission of a corrective action plan, as well as requiring the completion of up to six hours of continuing education courses in subject matter specified in the order of abatement.

Implementation of SB 151

Senate Bill 151 (Burton) repeals the triplicate prescription requirement for Schedule II controlled substance prescriptions and replaces it with a tamper resistant prescription form that may be obtained from approved printers. This new form will be required for all controlled substance prescriptions after a phase-in period. The bill also will require pharmacies to report Schedule III controlled substance prescriptions to the CURES system.

Because of the expansive nature of the changes required by SB 151, the new requirements will be phased in over a 12-month period. The following is a calendar outlining when the most significant elements of the bill become effective.

January 1, 2004

- The Board of Pharmacy (board) and the Department of Justice (Department) may approve security printers to produce the new controlled substance prescription forms.
- Permit mail order pharmacies to apply the prescription requirements of the state in which the patient resides when filling prescriptions.
- Controlled substance prescriptions (Schedules II-V) are valid for six-months.
- Requires all pharmacies to report Schedule II controlled substance prescriptions to the Department in a time and manner of the Department's choosing.
- Requires that Schedule III-IV controlled substance prescriptions be signed and dated by the prescriber.
- Controlled substance prescription forms may be acquired from approved security printers.
- Requires controlled substance prescription forms to have the following features:
  (1) Latent "void" protection so that if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
  (2) Watermark with the text "California Security Prescription" printed on the back of the prescription.
  (3) Chemical void protection that prevents alteration by chemical washing.
  (4) Feature printed in thermo-chromic ink (the ink changes color when exposed to heat).
  (5) Feature using micro printing (the text becomes a line if the prescription is copied or scanned).
  (6) Description of the security features included on each prescription form.
  (7) Quantity check off boxes printed on the form in the following quantities: 1-24, 25-49, 50-74, 75-100, 101-150, 151 and over.
  (8) Either of the following statements:

(a) "Prescription is void if more than one controlled substance prescription is written per blank" or
(b) Contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
(9) The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.
(10) A check box indicating the prescriber's order not to substitute.
(11) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

July 1, 2004

- The Department may no longer produce or distribute triplicate prescription forms.
- Triplicate prescription forms may be used to prescribe Schedule II controlled substances.
- Prescribers may use the new controlled substance prescription forms for Schedule II controlled substance prescriptions.
- Oral and electronic orders for Schedule II controlled substance prescriptions for patients in skilled nursing facilities, intermediate care facilities, home health care programs, and hospice programs are permitted. Such orders must be reduced to hard copy form and signed by the pharmacist on a form of the pharmacy's design.
- Requires prescribers dispensing Schedule II controlled substances to report those prescriptions to the CURES system.

January 1, 2005

- Triplicate prescription forms are no longer valid.
- All written controlled substance prescriptions (oral and fax orders for Schedules III-V are still permitted) shall be on controlled substance prescription forms.
- Pharmacies must report Schedule III controlled substance prescription information to the CURES system.
- Prescribers dispensing Schedule III controlled substances must report those prescriptions to the CURES system.

Compounding Issues – Labels and Central Fill

The Enforcement Committee received a request from the compounding pharmacists of the California Pharmacists Association (CPhA) to discuss two issues. The first issue involved the appropriate content label of compounded products. While the current label requirements reflect information that is needed by consumers when they receive compounded products, the problem arises when the compounded product is provide in multiple units of a dosage form for which individual product labels are either not feasible, cost prohibitive or a hindrance to treatment.

CPhA surveyed some pharmacists, and it was their opinion that it should be left to the individual judgment of the compounding pharmacist as to what should be included on individual units of compounded products. In many cases, individual doses should contain some sort of label to

indicate active ingredients. It was explained that the form of the label will vary depending on the dispensing unit and available space. In other cases, it was their opinion that a label on individual doses would result in little or no benefit and will cause more problems than it solves. In the case of compounded tablets and capsules, identification of any kind on individual doses isn't practical. However, in any case, the patient should be made aware of the situation and advised to always keep the doses in the box, bag or container in which it was dispensed and which it is labeled with the information that may be needed by a family member or emergency personnel in the even of a problem.

It was requested that the existing law be clarified and a dialog initiated to reach a reasonable and agreeable guideline for labels on compounded products. The Enforcement Committee responded that an ad hoc committee is going to be formed with the Department of Health Services to address issues of compounding. The committee will begin meeting next year. It was suggested to CPhA that they draft guidelines for discussion with the ad hoc committee.

The second issue was on compounding in central fill pharmacies. It was explained that many pharmacists and pharmacies specialize in compounded products. For a large number of these compounded products, similar systems and facilities are needed to assure consistency in preparation and potency. Pharmacies that specialize in this practice have invested in those systems and facilities and the products that are compounded are accepted as effective and safe.

Compounding pharmacists want to increase the access to compounded products by allowing compounding pharmacies to act as central fill pharmacies in the same way as is allowed for other prescriptions under CCR, title 16, section 1707.4. Moreover, a similar activity is currently allowed for paternal products pursuant to Business and Professions Code section 4123. The compounding pharmacists requested that the Board of Pharmacy move forward on this proposal to allow central compounding pursuant to 1707.4.

There was discussion that this issue should also be referred to the ad hoc committee on compounding and it was questioned whether this proposal could be adopted through regulation or would require legislation. The Enforcement Committee advised the proponents that it would place this issue on the October board agenda should they decide to present a legislative proposal for the board's consideration. **(Attachment F)**

Enforcement Committee Meeting Summary of September 17, 2003 (Attachment G)

Enforcement Team Meeting Summary of September 17, 2003 (Attachment H)

Report on Enforcement Actions (Attachment I)

Report on Committee Strategic Objectives for 2003/2004 (Attachment J)

Attachment A

State of California Department of Consumer Affairs

Memorandum

To: Patricia Harris
Executive Officer

Date: July 15, 2003

From: Paul Riches

Subject: Statutory History for B&P 4343

Business and Professions Code 4343 establishes a prohibition on the use of signage that includes words such as "pharmacy," "drugstore," "apothecary," or words of similar import unless the premise is a licensed pharmacy.

> 4343. No building shall have upon it or displayed within it or affixed to or used in connection with it a sign bearing the word or words "Pharmacist," "Pharmacy," "Apothecary," "Drugstore," "Druggist," "Drugs," "Medicine," "Medicine Store," "Drug Sundries," "Remedies," or any word or words of similar or like import; or the characteristic symbols of pharmacy; or the characteristic prescription sign (Rx) or similar design, unless there is upon or within the building a pharmacy holding a license issued by the board pursuant to Section 4110.

History

The origin of this prohibition is found in a 1905 statute (Chapter 406) that established a general regulation of pharmacists. The following was included in Section 1 of that act:

> "Every store or shop where drugs, medicines, or chemicals are dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded, which has upon it or in it as a sign the words "pharmacist," "pharmaceutical chemist," "apothecary," "druggist," "pharmacy," "drugstore," "drugs," or any of these words, or the characteristic showbottles or globes, either colored or filled with colored liquids, shall be deemed a "pharmacy" within the meaning of this act."

This provision essentially brings existing "pharmacies," by whatever name, under the board's regulatory authority. This is an inclusive statute designed to assert the board's jurisdiction over existing businesses.

The 1905 statute was amended in 1927 (Chapter 599) to that adds a prohibition on the use of "drug" or "drugs" in advertisements or displays in businesses that were not operated by a pharmacist.

> "Every store or shop where drugs, medicines, or chemicals are dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded, which has upon it or in it as a sign the words "pharmacist," "pharmaceutical chemist," "apothecary," "druggist," "pharmacy," "drugstore," "drugs," or any of these words, or the characteristic showbottles

or globes, either colored or filled with colored liquids, shall be deemed a "pharmacy" within the meaning of this act, and no store or shop shall use the word drug or drugs in any advertisement, or display unless a licentiate is in charge."

The 1907 statute was entirely rewritten in 1937 (Chapter 399) in a bill that codified the Pharmacy Law in the Business and Professions Code. The restrictions that were established in the 1905 and 1927 statutes were split into sections 4035 and 4037. This statute did not make substantive changes to these provisions. The 1937 statute also directly defined "pharmacy" for the first time and established a registration scheme for pharmacies. Prior legislation simply required that each store providing drugs was subject to the board's jurisdiction and must be in the charge of a pharmacist.

4035. As used in this chapter, pharmacy means and includes every store or shop where drugs, medicines or chemicals are dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded, which has upon it or in it as a sign the words "pharmacist," "pharmaceutical chemist," "apothecary," "druggist," "pharmacy," "drug store," "drugs," or any of these words.

4037. No store or shop shall use the words "drug" or "drugs" in any advertisement or display unless a registered pharmacist or a licentiate is in charge.

The addition of "licentiate" is not substantive in the context of this history. The 1937 statute draws a distinction between pharmacists licensed prior to its implementation and those licensed after. A "registered pharmacist" described pharmacists licensed under the apprentice system that existed prior to 1937 and a "licentiate in pharmacy" generally was a pharmacist licensed based on a licensing scheme much like the one that exists now for pharmacists (formal education, experience, and board examination).

Sections 4035 and 4037 were amended in 1947 (Chapter 931) to add the words denoting pharmacies in Section 4035 as reserved names that may only be used by a pharmacy. These amendments mark a change from an inclusionary statute defining pharmacy to an exclusionary statute that reserved use of those names for licensees.

4035. As used in this chapter, "pharmacy" means and includes every store or shop where drugs, medicines or medicinal poisons ~~chemicals~~ are dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded, which has upon it or in it as a sign the words "pharmacist," "pharmaceutical chemist," "apothecary," "druggist," "pharmacy," "drug store," "drugs," "drug sundries," "prescriptions," or any of these words, or any combination of these words.

4037. No store or shop shall use any ~~the~~ words or combination of words enumerated in Section 4035 ~~"drug" or "drugs"~~ in any advertisement or display unless a registered pharmacist or a licentiate is in charge.

The Pharmacy Law was substantially revised in 1955 (Chapter 550) to make minor changes in Section 4035 defining "pharmacy" and moved the prohibition formerly contained in Section 4037 to Section 4391.

4035. As used in this chapter, "pharmacy" means and includes every store or shop where drugs~~, medicines~~ or medicinal poisons are dispensed or sold at retail~~,~~ or displayed for sale at

retail, or where prescriptions are compounded, which has upon it or in it, as a sign the words "pharmacist," "pharmaceutical chemist," "apothecary," "druggist," "pharmacy," "drug store," "drugs," "drug sundries," "prescriptions," or any of these words, or any combination thereof. ~~of these words.~~

4391. No store or shop shall use any words or combination of words enumerated in Section 4035 in any advertisement or display unless a registered pharmacist ~~or a licentiate~~ is in charge.

In 1965 (Chapter 1822) Section 4035 was entirely rewritten to define "pharmacy" as a place or premise licensed by the board as a pharmacy. The new section also exempted hospitals from licensure as pharmacies and defined narcotics. All reference to reserved words was eliminated in this rewrite of Section 4035.

Section 4391 was rewritten by the same bill to eliminate reference to Section 4035 and to enumerate and expand words reserved for pharmacies to words of similar import and symbols denoting a pharmacy.

~~4391. No store or shop shall use any words or combination of words enumerated in Section 4035 in any advertisement or display unless a registered pharmacist is in charge.~~
4391. No building shall have upon it or displayed within it or affixed to or used in connection with it a sign bearing the word or words "Pharmacist," "Pharmacy," "Apothecary," "Drugstore," "Druggist," "Drugs," "Medicine," "Medicine Store," "Drug Sundries," "Remedies," or any word or words of similar or like import; or the characteristic symbols of pharmacy; or the characteristic prescription sign (℞) or similar design, unless there is upon or within the building a pharmacy holding a permit issued by the board pursuant to Section 4080 of this code.

In 1996, Section 4391 was moved and subject to technical amendments in Assembly Bill 2802 (Chapter 890, Statutes of 1996). This legislation was a comprehensive reorganization of the Pharmacy Law and moved the provisions of Section 4391 to Section 4343.

4343. No building shall have upon it or displayed within it or affixed to or used in connection with it a sign bearing the word or words "Pharmacist," "Pharmacy," "Apothecary," "Drugstore," "Druggist," "Drugs," "Medicine," "Medicine Store," "Drug Sundries," "Remedies," or any word or words of similar or like import; or the characteristic symbols of pharmacy; or the characteristic prescription sign (Rx) or similar design, unless there is upon or within the building a pharmacy holding a license issued by the board pursuant to Section 4110 ~~4080 of this code~~.

BILL LOCKYER
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DEPARTMENT OF JUSTICE

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October 17, 2003

The Honorable Richard Alarcon
Senator, Twentieth District
State Capitol, Room 4035
Sacramento, CA 95814

RE: Opinion No. 03-601

Dear Senator Alarcon:

By letter dated May 15, 2003, you requested an opinion of the Attorney General concerning the position of the federal Food and Drug Administration (FDA) with respect to the importation of prescription drugs from Canada. We have recently learned that the FDA is now in litigation regarding the issues raised by your request. It has long been our policy to decline to issue opinions on matters that may be judicially resolved. (See 66 Ops.Cal.Atty.Gen. Foreword (1983).) For this reason, we are canceling the assignment to prepare Opinion No. 03-601.

However, please find enclosed a copy of the August 25, 2003 letter from the FDA setting forth its position on the questions that you submitted.

Sincerely,

RODNEY O. LILYQUIST
Senior Assistant Attorney General
Chief, Opinion Unit

For BILL LOCKYER
Attorney General

ROL:jmn
Enclosure

cc: Gregory L. Gonot

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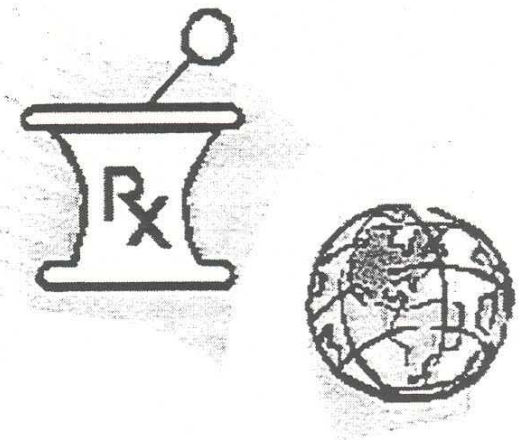
What You Should Know Before Buying Drugs From Foreign Countries or Over the Internet



September 2003

Purchasing Prescription Drugs from Foreign Countries and Reducing Drug Costs

The prices of prescription drugs are high. Some patients go without food in order to purchase their medications or reduce the quantity of prescription drugs they are supposed to take to make a supply of medication last longer. Other patients simply don't purchase medication prescribed for them because it is too expensive.

Today, many patients are seeking lower priced drugs from nontraditional sources – places other than their local pharmacies. Some patients are purchasing prescription drugs from foreign countries, typically Canada or Mexico, because the prices are lower. Other patients are purchasing drugs online, from companies they do not know. Some patients purchase these drugs online without a prescription written for them by a health care provider.

Can you purchase drugs for lower prices? What should you know about purchasing drugs from foreign countries? What about purchasing drugs over the Internet? Do you really need a prescription before you obtain prescription drugs? The following information may help you in making wise choices.

Frequently Asked Questions

Q Can I bring prescription drugs I buy outside the USA into the country legally?

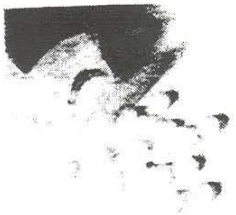
A The Federal Food and Drug Administration (the FDA) regulates prescription drugs made in the USA. Under federal law it is illegal for anyone except a drug manufacturer to import prescription drugs into the USA. There are strict requirements on drug manufacturers who import drugs.

These import laws were established for consumer protection – so that the only drugs available in the USA have been made by companies approved by the FDA, and have been manufactured at locations inspected by the government to produce the specific drugs. These laws are important for consistency – and uniformity – so that a specific drug has the same ingredients, strength, and will act in the same way regardless of who manufactures the drug or when the drug was made. This is important because it means the strength of the drug will be the same for every dose.

"Prescription drugs" means those drugs that are considered so dangerous that they may be sold only after a health care provider (for example, a doctor or nurse) has examined a patient and ordered the drug for the patient. The order is typically called a prescription. Consumers cannot legally purchase the prescription drugs without an order or prescription from a health care provider who has examined the patient.

"Over the Counter Drugs" (or OTC drugs) are the drugs that you can buy without a prescription (for example, aspirin or cold medicines). Consumers can go to a store and select OTC drugs themselves.

Frequently Asked Questions (continued)



Such consistency in your medication is important for health care providers to treat you, and for you to receive the drug treatment planned and prescribed for you.

However, the FDA does not always enforce provisions for importing prescription drugs. Sometimes prescription drugs that are not FDA approved for sale in the USA are allowed in the USA on "humanitarian grounds" to treat serious conditions such as AIDS before the drugs are approved for use in the USA. Also, in the past the FDA has not enforced pr visions against those who obtain a 90-day supply of medication for their personal use.

Q Why are prescription drug prices lower in other countries than here at home?

A There are a number of reasons. Among them: some governments set maximum drug prices for prescription drugs which holds down drug prices. In the USA, the government does not set maximum prices overall for prescription drugs. Also, typically the costs of researching and developing new drugs are passed on to American customers as part of a drug's price.

Q Why are prescription drug prices different at the local pharmacies in my neighborhood?

A There are a number of reasons – among them:

- *Volume discounts* -- some pharmacies can purchase drugs from wholesalers at lower prices than other pharmacies, based on the quantities of drugs sold or whether the pharmacy is part of a buying group with other pharmacies.

- *Rebates* – money is sometimes paid to pharmacies by drug manufacturers for sales of particular drugs. Not all pharmacies may get these rebates.

- *Overhead* -- charges that cover the expenses for the operations of the pharmacy and the services provided by the pharmacy.

Q Are the drugs I get from a foreign country lower in quality or strength?

A The drugs you obtain this way may be of the same quality as those you get in the USA – the prescription drugs may even have been manufactured here. However, you cannot tell what the drug is just by looking at it. If the drugs are counterfeit, are of a different strength, have been stored improperly or are not really the drugs the label says they are, a patient using such drugs could suffer serious health problems.

Is the Internet a good way to purchase prescription drugs?

Sometimes. Be cautious and careful.

- Make certain you are dealing with a pharmacy, and not another type or unknown form of drug supplier. Some businesses operating what appear to be Internet pharmacies are not pharmacies at all.
- Learn where the company is located – it may be located outside the USA in a country you know little about and where there is little government regulation of drug supplies.
- Beware if you do not need a prescription to purchase prescription drugs. The requirement for a prescription from a health care provider who has examined you is a legal requirement that exists to protect your health.
- Be careful if you must provide personally identifiable information (health information, social security number, credit card numbers) -- identity theft is a growing problem and you may not know to whom you are providing this sensitive and important personal information.
- Evaluate all costs for purchasing the drugs this way – it may not be cheaper after all.
- Purchase prescription drugs only from sites that are certified by national organizations – like the National Association of Boards of Pharmacy VIPPS seal on the Web site (the California Board of Pharmacy can help you with this information).
- Advise your health care provider if you obtain prescription drugs this way.

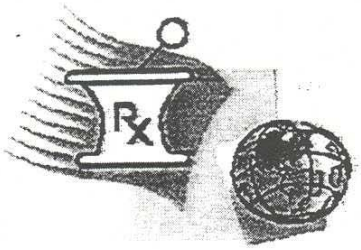
Before buying drugs from a foreign country or over the Internet, carefully consider your options.

- Beware of any changes in your health after taking any drug obtained this way. If there is a change or if you feel differently, talk to your health care provider.
- Consider whether you want to give a credit card number to a company that is making these purchases for you.
- Determine the handling and other extra fees you pay for imported prescription drugs. How much will you really save?
- Ask any company that orders prescription drugs for you what it will do if there is a problem with the medication you receive.
- Keep your health care provider informed.

For further assistance, please contact:

California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, California 95814
Phone: (916) 445-5014

Or visit us on the web at:
www.pharmacy.ca.gov



Tips to Save You Money When Buying Prescription Drugs

How can I reduce the amount I pay for prescription drugs?

1. **Shop around and ask for the lowest price**

   Call various pharmacies and ask each of them how much it would cost to purchase your prescription medication at that pharmacy. Don't be shy -- let them know you are comparison shopping. Write down the prices you are quoted by each pharmacy.

2. **Consider Generics**

   Ask your pharmacist or your health care provider if a generic drug can be prescribed instead of a brand-name drug. Generic drugs can save you a lot. The active ingredients in generic drugs are chemically identical to the active ingredients in brand name drugs. Generic drugs are available after a patent has expired on a brand name drug. When this occurs, other drug manufacturers can make and sell the drug. Generic drugs are not inferior to the brand name drug, but they often are much less expensive.

3. **Consider a therapeutically similar drug**

   Ask your pharmacist or health care provider if another drug would have the same therapeutic effect as a more expensive drug that has been prescribed for you. Sometimes your condition can be treated with another drug that is less expensive.

4. **Beware of prescription drugs advertised to consumers**

   Today many drug companies advertise prescription drugs directly to the public, recognizing that patients then will ask their health care providers to prescribe these drugs to them. These drugs are often new, brand name drugs, and expensive. Instead ask your pharmacist or health care provider if there are other drugs that could provide the same therapy for a lower cost.

5. **Do not skip doses or reduce the amount of prescription drugs you are supposed to take to make medication last longer**

   Sometimes patients take less of the medication they are prescribed so that the drugs will last longer. This can include skipping doses or taking only one-half of a pill. However, reducing the amount of medication you are supposed to take can interfere with your drug therapy and actually harm you. Don't reduce your medication without talking to your pharmacist or health care provider.

6. **Learn if you qualify for special, low cost drug programs operated by governmental agencies, drug companies, insurance companies or others**

   Do you have insurance that can cover a portion of your drug costs? Do you qualify for government or drug-company operated programs that can reduce drug expenses? The other side of this fact sheet contains a list of these programs.

7. **Purchase a greater quantity of medication at one time**

   Ask the pharmacy if you can reduce your total drug costs if you purchase drugs for a longer period of time; for example, purchase a 60-day supply instead of a 30-day supply. You may also be able to obtain a higher dose of a drug for about the same price and then split the medication. However, pill splitting is not possible for some medication (like sustained release drugs) or for some patients. Ask your pharmacist or health care provider first.

8. **Keep a list of all medication you take**

   Make a list of all prescription drugs you take and who prescribed them. Also include all nonprescription drugs you take (like aspirin, nasal spray, antacids, cold medication — drugs that do not require a prescription). Also, add to the list any herbal and food supplements you take. Be sure to share this list with your health care providers and pharmacist every time a prescription is written or filled for you. Don't be shy about sharing this list -- sometimes these drugs combine to cause harmful effects and this information could save your life or prevent duplicate drug therapy.

September 2003

For further information, please contact:

California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, California 95814
(916) 445-5014
www.pharmacy.ca.gov

Resources for Discounts on Prescription Drugs

DISCOUNT PROGRAMS	QUALIFICATIONS & GENERAL INFORMATION
MEDICARE DISCOUNT PROGRAM Available at any pharmacy currently providing Medi-Cal services, including chain and independent pharmacies.	Medicare recipients are eligible to obtain their medications at the Medi-Cal reimbursement rate. The discount ranges from 10% to 40% and depends on the type of medication dispensed – generic or the brand name. To qualify, you must be a Medicare enrollee, and must pay for the entire cost of the prescription in full without prescription drug coverage.

PHARMACEUTICAL COMPANY PROGRAMS	QUALIFICATIONS & GENERAL INFORMATION
TOGETHER RX CARD 1-800-865-7221 www.togetherrx.com	A joint discount card from prescription drug manufacturers Novartis, Abbott, Astra Zeneca, Aventis, Ortho-McNeil, Bristol-Myers-Squibb, GlaxoSmithKline, and Janssen pharmaceuticals. Discounts vary from 20% - 40%. To qualify you must be a Medicare enrollee, do not have prescription drug coverage, and your annual income cannot exceed $28,000 for an individual or $38,000 for couples. The program includes generic treatments produced by the above manufacturers.
ORANGE CARD GlaxoSmithKline 1-888-672-6436 www.gsk.com/index.htm	GlaxoSmithKline's medical savings program for seniors. Discounts average 30%. To qualify you must be a Medicare enrollee, do not have prescription drug coverage, and your annual income cannot exceed $30,000 for an individual or $40,000 for couples.
PFIZER SHARE CARD 1-800-717-6005 www.pfizerforliving.com/sharecard	A discount for Pfizer products. $15 for each 30-day supply. To qualify you must be a Medicare enrollee, do not have prescription drug coverage, are not eligible for Medicaid or any other drug benefit program funded by the state, and your annual income cannot exceed $18,000 for an individual or $24,000 for couples.
LILLY ANSWERS 1-877-795-4559 www.lillyanswers.com	A discount for all Lilly products except controlled substances. To qualify you must be a senior or someone with a disability enrolled in Medicare, have no other prescription drug coverage through a health plan, insurance plan, or Medi-Cal, and your annual income cannot exceed $18,000 for an individual or $24,000 for couples.

PHARMACY PROGRAMS	QUALIFICATIONS & GENERAL INFORMATION
LONGS DRUG STORES For details, contact your local Longs Drug Store or online at www.longs.com	Longs offers a Senior Advantage Program in which the pricing plan is identical to the Medicare Discount Program. The program also includes discounts on Longs products and services. There is no fee to join and you do not need to be a Medicare enrollee. Longs accepts most discount card plans.
RITE AID www.riteaid.com	Rite Aid accepts most discount card plans such as the Pfizer card, Together Rx, and GlaxoSmithKline.
WALGREENS www.walgreens.com	Walgreens has a Senior Dividends Discount Card. No fee for the card. Each time a prescription is purchased a dollar amount to 10% off the retail price is credited toward the card. The credit balance may be used for other purchases at Walgreens (except selected items where prohibited by law).

PHARMACY PROGRAMS	QUALIFICATIONS & GENERAL INFORMATION
MED AMERICA PHARMACY 1-209-475-1020 www.medamericapharmacy.com	For a membership fee of $1 per month, individuals age 60 and older may save an average of 30% or more on medications. The pharmacy can also help you enroll in other prescription drug programs such as Together Rx and Pfizer Share Card.
DISCOUNT WAREHOUSES For details and prices check with your local discount warehouse.	It may be beneficial to check with your local discount warehouses for prescription drug prices. While they often to do not participate in programs such as the Medicare discount, in order to remain competitive, prescription drug prices may be similar or lower than discount drug programs.

INTERNET RESOURCES	GENERAL INFORMATION
BENEFITS CHECKUP www.benefitscheckup.org	Assists seniors in locating programs that may pay for some of the costs associated with prescription drugs, health care, utilities, and other essential items or services.
FIRSTGOV FOR SENIORS www.seniors.gov/health/drugs.asp	Select "Prescription Drugs" link. Allows the user to research up to 5 pharmaceutical companies at a time to determine if the pharmaceutical company offers a prescription drug discount program. The user may also search up to 5 health conditions or diseases at a time to view programs for specific health conditions.
CALIFORNIA HEALTHCARE FOUNDATION www.chcf.org	An online resource for independent research, analysis, and news on issues affecting healthcare and financing. Select the "prescription drug" topic. This section offers a comparative guide for 10 different plans to assist individuals with their prescription drug costs.
MEDICARE www.medicare.gov/prescription/home.asp	Allows a search by geographic area or zip code to access local program and plan information for prescription assistance. This site provides information on public and private programs that offer discounted or free medication, as well as Medicare Health plans that include prescription coverage.
PhRMA www.helpingpatients.org	This is a link to the Pharmaceutical Research and Manufacturers of America (PhRma) Web site that helps individuals obtain information on manufacturer assistance programs only.
RX ASSIST www.rxassist.org	This Web site offers information on manufacturer and state programs. The Robert Wood Johnson Foundation runs it.
MEDICARE RIGHTS CENTER www.medicarerights.org	Select the "Discount Rx Resources" topic. It contains eligibility and benefit information on state prescription drug assistance programs, drug discount cards, and internet and mail order discount pharmacies. The Web site also provides additional information regarding the Medicare discount program.

FDA News

FOR IMMEDIATE RELEASE
P03-73
September 29, 2003

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

FDA/U.S. Customs Import Blitz Exams Reveal Hundreds of Potentially Dangerous Imported Drug Shipments

A recent series of spot examinations of mail shipments of foreign drugs to U.S. consumers conducted by the Food and Drug Administration (FDA) and U.S. Customs and Border Protection (CBP or Customs) revealed that these shipments often contain dangerous unapproved or counterfeit drugs that pose potentially serious safety problems. This joint operation was carried out to help FDA and CBP target, identify, and stop counterfeit and potentially unsafe drugs from entering the United States from foreign countries via mail and common carriers. It was also designed to help FDA and CBP assess the extent of this problem.

These “blitz” exams were conducted in the Miami and New York (JFK) mail facilities from July 29-31, 2003, and the San Francisco, and Carson, Calif., mail facilities from August 5-7 2003, to obtain a representative picture of products entering the United States. In each location, packages shipped by international mail through U.S. Postal Service facilities over a 3-day time span were examined. For the purposes of these blitzes FDA and CBP identified, through review of historical data and experience, those packages likely to contain drug products. For example, packages were considered if they were from countries from which drugs are known to be exported via the mail. Due to the speed at which parcels are automatically processed and transported through the mail facilities, country of origin was the only specific criterion that could be consistently applied to all parcels.

Approximately 100 parcels (each of which may have contained multiple drug products) per day per facility were selected based

upon their country of origin and historical experience. They were subsequently opened by CBP and jointly examined by both Agencies. Those in violation of CBP provisions were held by CBP. Those in violation of FDA regulations were detained by FDA.

In general, FDA and CBP do not have sufficient resources to perform comprehensive examinations of all mailed packages due to the huge volume of parcels entering the United States through international mail and courier services, the consuming time requirements for processing and returning illegally imported drugs, and multiple, competing enforcement priorities. For example, the Carson, Calif., mail facility alone receives over 10,000 parcels per day.

Although many drugs obtained from foreign sources purport, and may even appear to be, the same as FDA-approved medications, these examinations showed that many are of unknown quality or origin. Of the 1,153 imported drug products examined, the overwhelming majority, 1,019 (88%), were violative because they contained unapproved drugs. Many of these imported drugs could pose clear safety problems.

These drugs arrived from many countries. For example,15.8% (161) entered the U.S. from Canada; 14.3% (146) from India; 13.8% (141) from Thailand; and 8.0% (82) from the Philippines. The remaining entries came from other countries.

“This joint effort with CBP illustrates the real and serious public health risks created by the importation of unapproved drugs,” said Mark B. McClellan, M.D., Ph.D., Commissioner of Food and Drugs. “To protect Americans from unsafe imported drugs, we are working to target our enforcement resources as effectively as possible against those products that pose a threat to the health of consumers and the safety and security of our drug supply.”

“This action represents an important step forward in keeping harmful or illegal drugs from entering the country,” said Customs and Border Protection Commissioner, Robert C. Bonner. “Although CBP’s priority mission is preventing terrorists and terrorist weapons from entering the United States, CBP continues to perform its traditional mission by working with the FDA to identify and interdict illegal and dangerous drugs that could threaten public health and safety.”

The potentially hazardous products found in these blitz exams revealed:

- **Drugs different from those approved by FDA** -- Drugs that FDA has never approved are being imported. For example, Roaccutane (an unapproved version of Accutane) is being imported from Thailand. In the United States, prescribers of Accutane (a drug to treat a severe form of acne) are required to monitor patients to avoid certain serious risks such as birth defects that may occur following use of the drug. Taro-warfarin (an apparently unapproved version of Warfarin) from Canada is also being imported. Warfarin is used to prevent blood clotting and its potency may vary depending on how it is manufactured. Because it can cause serious, life-threatening bleeding if not administered appropriately, it requires careful monitoring by a health care provider of a patient's blood count during treatment.
- **Drugs requiring careful dosing** -- Drugs such as unapproved versions of Dilantin (from Philippines); unapproved versions of Synthroid (from Canada); and unapproved versions of Glucophage (from Canada and Philippines) that require individual titration and
  very careful dosing to avoid serious life-threatening side effects are being imported.
- **Drugs with inadequate labeling** -- Moreover, most of these drugs came without adequate labeling or instructions for proper, safe use. Some of the drug labeling was not in English and important information about matters such as proper dosage was often missing.
- **Drugs inappropriately packaged** -- In some cases, these drugs were inappropriately packaged in baggies, tissue paper, or letter envelopes. In other instances, the imported drugs arrived crushed and broken.
- **Drugs withdrawn from the market** -- Consumers are importing drugs that FDA has withdrawn from the market for safety reasons. For example, one unapproved drug that came from Mexico, Buscapina, appears to be the drug Dipyrone that was removed from the U.S. market in 1977 because of several reports of the development of severe blood disorders following the drug's administration, some of which resulted in fatalities;
- **Animal drugs not approved for human use** -- Animal drugs that FDA has not approved for humans use are being imported. For example, Clenbuterol, a drug approved for the treatment of airway disease in horses but that has not been approved for human use and has been banned by the International Olympic Committee as a performance enhancing drug, came from Costa Rica and China;
- **Drugs with dangerous interactions** -- Drugs such as ketoconazole (from Thailand) – unapproved versions of Viagra

(from United Kingdom, India, Philippines and Japan); and unapproved versions of Zocor (from Canada) are being illegally imported and have the potential to cause clinically significant interactions with other drugs which consumers may be taking;

- **Drugs that carry risks requiring initial screening and/or periodic patient monitoring** -- Drugs such as unapproved versions of Lipitor (from Ireland, Thailand, Japan, Philippines, Canada, Argentina, New Zealand, England and Brazil); and unapproved versions of Pravachol (from Canada) are being illegally imported. Initial screening and periodic patient monitoring by a medical professional (e.g. monitoring liver function) are recommended in FDA's approved labeling for these drugs to help assure their safe use;
- **Controlled substances** -- Over 25 different controlled substances were offered for import including Diazepam (from Canada, Thailand, Philippines, Costa Rica, Malaysia, New Zealand, and India); Xanax (from Philippines); Codeine (from Canada, Philippines, Costa Rica, United Kingdom, New Zealand, Thailand, Guatemala, China, Peru, and Taiwan); Valium (from Philippines and Thailand); and anabolic steroids (from Costa Rica). These drugs were referred to the Drug Enforcement Administration. Controlled substances pose serious safety issues for consumers because they are dangerous narcotics that have abuse potential for patients who take them inappropriately or without the proper physician supervision.

The blitz is also helpful in understanding trends in the illegal importation of unsafe drugs. In 2001, FDA conducted a similar analysis that prompted the same concerns about the risk of these imported drugs. Compared to the 2001 results at the Carson mail facility, this most recent blitz uncovered a somewhat larger number of imports, including a larger number of unapproved drugs and drugs that appeared to be counterfeits. The blitz FDA conducted at the Carson mail facility in 2001, as well as the most recent blitz conducted by FDA in coordination with Customs, illustrate the type of regular surveillance activities involving imported drug products that FDA undertakes. As a result of the current blitz, we are re-evaluating the enforcement strategies and objectives we use to target the entry of unapproved and/or counterfeit drug products through international mail facilities.

"There is no evidence that unapproved imported drugs are becoming any safer or more reliable," said Dr. McClellan. "Given FDA's limited resources and authorities to detect and block potentially unsafe imports, we are concerned about any measures

that would increase the flow of these unapproved drugs, or provide easier channels for them to enter the United States."

The blitz results will assist the Agency in its efforts to:

- Utilize its investigatory and regulatory resources more strategically to focus on the foreign sources of illegal, unsafe imported drugs;
- Identify shipping patterns specific to identified sources of unsafe drugs so that it can target future shipments and sources of such drugs; and
- Seek out partnerships with other federal and state agencies to combat this problem.

In addition, FDA will continue its efforts to educate the public about the dangers of drugs through illegal, poorly-regulated, and potentially unsafe foreign channels.

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FOR IMMEDIATE RELEASE **Media Inquiries: 301-827-6242**

P03-65 **Consumer Inquiries: 888-INFO-FDA**

September 9, 2003

FDA TAKES ACTION AGAINST COMPANIES THAT ARE IMPORTING UNAPPROVED, POTENTIALLY UNSAFE DRUGS

The Food and Drug Administration (FDA) has asked the Department of Justice to file a complaint for injunction against Rx Depot, Inc., and Rx of Canada, LLC (Rx Canada), to stop them from importing drugs that pose a serious threat to the public health. FDA has uncovered a disturbing pattern of actions by these companies resulting in potentially hazardous errors.

"FDA is compelled to act, as have other state health authorities, against this significant public health risk," said FDA Commissioner Mark B. McClellan, MD, Ph.D. "While we will continue to take every step possible under the law to help Americans get access to safe and effective, affordable medicines, we cannot and will not stand by and let aggressive companies profit through illegal actions that put the health of Americans at risk." In addition to FDA's action today, the states of Oklahoma, Arkansas, and Montana have also taken action against the companies involved.

On March 21, 2003, FDA sent Rx Depot a warning letter (www.fda.gov/foi/warning_letters/g3888d.pdf) informing the firm that, "Your actions also present a significant risk to public health, and you mislead the public about the safety of the drugs obtained through Rx Depot" and that it risked possible enforcement action if it continued to promote sales of unapproved drugs, claiming that they were "FDA-approved" and "exactly the same as if purchased in the United States." Despite this warning, the defendants have stated that they will continue their activities until ordered by a court to stop. These companies' aggressive and continuing violations of a fundamental public health law creates significant, potential health risks associated with buying unapproved and illegally imported medicines from unregulated sources.

Rx Depot originally came to the attention of the FDA through its work with the states and

because of RX Depot's aggressive and misleading promotion of sales of unapproved drugs to Americans for profit. During the course of investigating Rx Depot's practices, FDA investigators made

undercover purchases of two products from Rx Depot's Oklahoma operation to determine the type and quality of products the firms were shipping to patients. The agency received drugs that were purported to be safe and effective, but were unapproved or illegally imported into the U.S., and potentially unsafe.

A particularly disturbing example was a 30-day prescription order placed with Rx Depot for Serzone, a powerful anti-depressant drug. An FDA investigator brought a prescription for Serzone to Rx Depot that called for 60 pills, with one pill to be taken twice each day for 30 days. Instead, the investigator received 99 pills of APO-Nefazodone, an unapproved, foreign-manufactured version of the active ingredient in Serzone. In addition, the APO-Nefazodone package did not indicate that more than the prescribed number of pills was sent; instead, the labeling simply instructed the patient to take one pill two times a day. If the patient took the drug as instructed by the package sent from the Canadian pharmacy, he or she could have an increased risk of liver failure, which might be associated with taking the drug for an excessive period.

"Unapproved drugs entering the United States through illegal channels pose a significant threat not only to good prescribing practices, but to the safety and security of the prescription drug supply in the United States," said Dr. McClellan. "FDA does not have the resources necessary to assure the safety of unapproved drugs imported into the United States. A long-distance international scheme that is deliberately out of compliance with U.S. and Canadian laws not only poses risks in itself; it also creates wide channels for criminals who only care about making a fast buck to exploit in bringing unsafe medications into the United States. Unapproved drugs are more likely to be contaminated, counterfeit, contain different amounts of active ingredients, or contain different ingredients altogether. Now more than ever, Americans need effective protections of the safety and integrity of their prescription drugs."

In light of such risks, FDA is alerting the American public to avoid purchasing drugs that come from any source operating outside the safeguards of systems established by the United States and governments of other nations to assure drug effectiveness, safety and purity. Recent attempts by others to introduce counterfeit drugs, controlled substances, drugs that pose special health risks, expired or otherwise subpotent drugs, and seriously mislabeled drugs into the American marketplace underscore the serious public health threats patients face without proper prescription drug safeguards. These safeguards are provided by a comprehensive drug safety system that FDA has developed based on Federal law and in conjunction with many other Federal and state authorities and health professional associations. This system provides critical safety assurances, at every step from drug manufacturing and distribution to appropriate prescribing and patient education, to help make sure that patients get the most benefits and avoid the important risks of prescription drugs.

The FDA has also taken many steps to help consumers meet their medication needs at a more affordable price, without compromising drug safety and effectiveness. These include the

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 25 2003

Mr. Gregory Gonot
Deputy Attorney General
State of California
Department of Justice
1300 I Street
Sacramento, California 95814

Re: Opinion No. 03-601

Dear Mr. Gonot:

I write in response to the letter of July 28, 2003, that your colleague, Rodney O. Lilyquist, sent the United States Food and Drug Administration (FDA) regarding the importation of prescription drugs from Canada into the State of California.

I. QUESTIONS PRESENTED

Mr. Lilyquist's letter asks nine separate questions about the potential liability associated with importing prescription drugs from Canada. All nine of the questions relate to one of three basic issues:

- Questions 1 – 6 query whether it is legal to purchase drugs from Canada and import them into the State of California.

- Questions 7 – 8 query whether the federal law in this area preempts the State of California (or a county or city within the state) from enacting a law that would legalize the importation of prescription drugs from Canada.

- Question 9 queries whether public pension funds such as CALPERS or CALSTRS can negotiate for Canadian prescription drug prices for their members.

II. SHORT ANSWER

FDA is very concerned about the safety risks associated with the importation of prescription drugs from foreign countries. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.- approved prescription drugs have been of unknown quality. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. For example, an American consumer recently ordered an FDA-approved anti-seizure medication called Neurontin from a website that purported to operate in

Canada and ship FDA-approved drugs from Canada into the United States. Nevertheless, the drug the consumer actually received had been manufactured in India, shipped from India, and was not approved by FDA for any use in the United States. In another instance, a website that purported to operate in Canada mailed insulin into the United States for use by an American with diabetes. Although the drug originally had been manufactured in the United States, it had not been appropriately refrigerated when shipped back into the country. The failure to refrigerate insulin promotes the degradation of the drug and renders it less effective. Unfortunately, however, the failure to refrigerate the product may not change its appearance, so American consumers may have no way of knowing their insulin has been mishandled abroad.

These safety concerns are reflected in the import provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which strictly limit the types of drugs that may be imported into the United States. Congress enacted these provisions to create a relatively "closed" drug distribution system, which helps ensure that the domestic drug supply is safe and effective. Accordingly, if an entity or person within the State of California (including any state, county, or city program, any public pension, or any Indian Reservation) were to import prescription drugs into the State of California from Canada, it would violate FFDCA in virtually every instance. Furthermore, the drug importation scheme set forth by Congress preempts the State of California (and any city or county within the state) from passing conflicting legislation that would legalize the importation of certain drugs from Canada in contravention of the FFDCA.

III. ANALYSIS

1. Questions 1 – 6: The importation of prescription drugs from Canada

General Legal Framework

The starting point for our analysis is the legal framework applicable to imports of prescription drugs from Canada.[1]

First, virtually all drugs imported to the United States from Canada violate the FFDCA because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements in the FFDCA is prohibited under 21 U.S.C. §§ 331(a), and/or (d).

FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. Generally, drugs sold outside of the United States are

[1] We will limit our discussion to drugs imported from Canada because your request is so limited. The legal analysis is the same for drugs imported from any foreign country.

not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the United States approval, and thus it is considered to be unapproved. 21 U.S.C. § 355. The version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 352(b)(2) but is not required in the foreign country, or it may be labeled in a language other than English (*see* 21 C.F.R. § 201.15(c)).

Second, with respect to "American goods returned," it is illegal for any person other than the original manufacturer of a drug to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FFDCA. *Id.* Importing a drug into the United States in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).

Thus, to ensure compliance with the FFDCA, any state or private entity that intends to import prescription drugs into the United States must ensure, among other things, that it only imports FDA-approved drugs that comply with the FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. The importer must also ensure that each drug meets all U.S. labeling requirements, and that such drugs are not imported in violation of the "American goods returned" language in 21 U.S.C. § 381(d)(1).

Practically speaking, it is extremely unlikely that any program in the state of California could ensure that all of the applicable legal requirements are met. Consequently, almost every time a city, county, or state program imported a drug from Canada, that program would violate the FFDCA. Moreover, individuals or programs that cause illegal shipments also violate the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited..."). Thus, neither the public nor private entities mentioned in Mr. Lilyquist's letter can avoid jurisdiction under the FFDCA by merely "facilitating" the sale of Canadian drugs to California citizens through a third-party internet service. [2]

With respect to questions 4 and 5 of Mr. Lilyquist's letter, please note that the preceding analysis applies also in the case of sovereign Indian nations located in the State of California. FDA considers Indian Reservations to be possessions of the United States within the meaning of 21 U.S.C. § 321(a)(2). Accordingly, FDA asserts complete jurisdiction over products within the purview of the FFDCA that are imported, purchased, or sold by an Indian reservation. *See FPC v. Tuscarora Indian Nation*, 362 U.S. 99, 116 (1960); *United States v.*

[2] The issue of whether persons may broker the sale of Canadian drugs through an internet operation is discussed more fully in Warning Letters that FDA sent to Rx Depot (March 21, 2003) and CanadianDiscountDrugs (June 30, 2003). A copy of those letters is enclosed and can also be obtained through FDA's website at www.fda.gov. They are particularly responsive to question number 6 in Mr. Lilyquist's letter, which queries whether an Indian nation may sell Canadian prescription drugs through a website to other residents of California.

Baker, 63 F.3d 1478, 1484 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 824 (1996); *United States v. Funmaker*, 10 F.3d 1327, 1330 (7th Cir. 1993); *EEOC v. Fond du Lac Heavy Equipment and Construction Co.*, 986 F.2d 246, 248 (8th Cir. 1993).

With respect to question 6 of Mr. Lilyquist's letter, please note also that the preceding analysis applies to persons who import drugs into the United States on their person or on a bus. In those cases where the FFDCA prohibits the importation of a prescription drug, it makes no legal difference whether that drug has been imported through the mails, delivered by a private shipping company, or carried across the border on one's person. *See* 21 U.S.C. §§ 331 and 381.

FDA's Personal Importation Policy

There has been some recent confusion in the press about whether FDA's Personal Importation policy changes the law with respect to personal imports of pharmaceuticals. Recent advertisements in certain domestic newspapers and magazines have implied that Congress has made the personal importation of drugs a legal practice. Other advertisements and certain Internet sites have stated that personal importation of up to a 90-day supply of prescription medications is legal. Neither of these messages is true.

The Personal Importation policy is used to help guide the agency's enforcement discretion with respect to imports by individuals of drugs for their personal use. Under certain defined circumstances, as a matter of enforcement discretion, FDA allows consumers to import otherwise illegal drugs. Under this policy, FDA may permit individuals and their physicians to bring into the United States small quantities of drugs sold abroad for a patient's treatment of a serious condition for which effective treatment may not be available domestically. This approach has been applied to products that do not present an unreasonable risk and for which there is no known commercialization and promotion to persons residing in the U.S. A patient seeking to import such a product must also provide the name of the licensed physician in the U.S. responsible for his or her treatment with the unapproved drug product. *See* FDA Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage of Personal Importation.

However, this policy is not intended to allow importation of foreign versions of drugs that are approved in the U.S., particularly when the foreign versions of such drugs are being "commercialized" to U.S. citizens. (Foreign versions are often what Canadian pharmacies offer to sell to U.S. consumers.) Moreover, the policy simply describes the agency's enforcement priorities; it does not change the law.

Potential Liability

There are many sources of civil and criminal liability for parties who violate the FFDCA. A court can enjoin violations of the FFDCA under 21 U.S.C. § 332. A person who violates the FFDCA can also be held criminally liable under 21 U.S.C. § 333. A violation of 21 U.S.C.

§§ 331(a), (d), or (t) may be prosecuted as a strict liability misdemeanor offense. *See United States v. Dotterweich*, 320 U.S. 277, 284 (1943); 21 U.S.C. § 333(a)(1). Any such violation that is committed with intent to defraud or mislead or after a prior conviction for violating the FFDCA may be prosecuted as a felony under 21 U.S.C. § 333(a)(2). Separately, it is also a felony to knowingly import a drug in violation of the "American goods returned" provision of 21 U.S.C. § 381(d)(1). *See* 21 U.S.C. § 333(b)(1)(A).

Those who can be found civilly and criminally liable include all who cause a prohibited act under the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited"). Those who aid and abet a criminal violation of the FFDCA, or conspire to violate the FFDCA, can also be found criminally liable under 18 U.S.C. §§ 2 and 371.

To date, FDA has focused its enforcement resources on those who commercialize the practice of importing drugs into the United States from abroad.[3] With respect to question 6 in Mr. Lilyquist's letter, please note that, as a matter of enforcement discretion, FDA generally has not seized drugs from those who have taken buses across the border and then brought foreign drugs back into United States for their own personal use. Instead, FDA has attempted to educate such citizens about the safety risks associated with consuming foreign drugs. Nevertheless, FDA retains the authority to bring an enforcement action in any case in which a provision of the FFDCA has been violated.

Please also note that, under current California law, state-sponsored importation of drugs from Canada for use in the state's Medi-Cal program may violate the statutory and regulatory requirements for this program. *See* West's Ann. Cal. Welf. & Inst. Code, § 14100, *et. seq*; Cal. Admin. Code tit. 22, § 50000, *et. seq*. For example, the importation of drugs from Canada may violate the Prudent Purchase of Drugs Program, 22 CCR § 51513.6, because the drug products are not "handled in accordance with the provisions of applicable federal and state law." In addition, we question whether the state would be potentially liable in tort if a California citizen were injured by a drug that the state purchased in violation of federal law. FDA has not researched and does not here advise you of any tort liability that may arise under state law, but we cite the issue as a possible concern.

2. Questions 7 and 8: Federal preemption

Federal preemption of state law is grounded in the Supremacy Clause of the United States Constitution. U.S. Const. art. VI, cl. 2. The Supremacy Cause states that: "This Constitution, and the Laws of the United States which shall be made in pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

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[3] *See, e.g.*, the Warning Letter that FDA sent to Rx Depot on March 21, 2003, the Warning Letter that FDA sent to CanadianDiscountDrugs on June 30, 2003, and the letter that FDA sent the Kullman Firm of New Orleans, Louisiana on February 12, 2003. A copy of the Kullman letter has also been enclosed for your review.

The Supreme Court has held:

> under the Supremacy Clause, the enforcement of a state regulation may be pre-empted by federal law in several circumstances; first, when Congress, in enacting a federal statute, has expressed a clear intent to pre-empt state law; second, when it is clear, despite the absence of explicit preemptive language, that Congress has intended, by legislating comprehensively, to occupy an entire field of regulation and has thereby left no room for the States to supplement federal law; and finally, when compliance with both state and federal law is impossible, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Capital Cities Cable, Inc. v. Crisp, 467 US 691, 698-99 (1984) (quotation marks and citations omitted); *see also English v. General Electric Co.*, 496 US 72, 78-79 (1990); *Association of Int'l Auto Mfrs., Inc. v. Abrams*, 84 F.3d 602, 607 (2nd Cir. 1996).

Courts have thus held that federal law preempts state law when, *inter alia*, Congress has intended to occupy a field of regulation comprehensively (termed "occupation of the field preemption") and when the federal law and the state law actually conflict (termed "implied conflict preemption"). *See English v. General Electric Co.*, 496 US at 78-79; *Choate v. Champion Home Builders Co.*, 222 F.3d 788, 792 (10th Cir. 2000).

Occupying the field

Congressional intent to occupy a field comprehensively can be shown any of three ways: 1) when, based on the pervasiveness of the federal regulation, it may be inferred that Congress "left no room for the States to supplement it"; 2) if the federal statute "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."; or 3) when the state regulation "may produce a result inconsistent with the objective of the federal statute." (emphasis added) *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 US 707, 713 (1985), *quoting Rice v. Santa Fe Elevator Corp.*, 331 US 218, 230 (1947).

In the instant matter, Congress set forth a comprehensive importation scheme in the FFDCA that strictly limits the types of prescription drugs that are allowed to be introduced into domestic commerce. For example, the "American goods returned" provision (21 U.S.C. § 381(d)(1)) was enacted in 1988 as part of the federal Prescription Drug Marketing Act. PL. 100-293 (April 22, 1988). In enacting the law, Congress cited the explicit goal of limiting the flow of drugs into the United States from abroad. In section 2 of the bill, Congress found, "[l]arge amounts of drugs are being reimported into the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping." *Id.* Clearly,

Congress enacted section 381(d)(1) and the other import provisions in the FFDCA with the goal of controlling the types of drugs that could be legally imported into the United States. The federal scheme is comprehensive in that it promulgates national standards that are to be applied equally to all ports of entry, regardless of the states in which they are situated. By definition, the scheme cannot allow the individual states to enact laws that erode the federal standards; otherwise, importers could simply circumvent the federal law by routing all their unapproved drugs into the state (or states) that allowed such imports. If the state of California were to enact a law that contravened the scheme, there is no question that the result would be inconsistent with the plain objectives of the FFDCA.

Implied conflict preemption

Implied conflict preemption can be shown in two ways: (1) where it is impossible to comply with both federal and state law; or (2) where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *See English v. General Electric Co.*, 496 US at 79.

In the instant matter, if the state were to enact import legislation that contravened the provisions of the FFDCA, those importing the drugs would find it impossible to comply with both the state and the federal law. Indeed, the drugs imported pursuant to the state law would still be illegal under federal law (*see* 21 U.S.C. §§ 331, 352, 353, 355, and 381), and those importing the drugs would be subject to civil or criminal liability in the federal courts (21 U.S.C. §§ 331, 332, and 333).

In addition, a state law authorizing the importation of certain drugs would frustrate the Congressional objectives enshrined in the import provisions of the FFDCA. As noted, Congress clarified the purpose behind 21 U.S.C. § 381(d)(1) when it passed the Prescription Drug Marketing Act. It concluded that American consumers are best protected by a "closed" drug system that strictly limits the types of products that may be imported into the United States. Any effort by the State of California to pass legislation conflicting with that scheme would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress as expressed in the FFDCA.

3. Question 9: Public Pension Funds

As noted above, the import prohibitions in the FFDCA apply to both public and private entities. *See* 21 U.S.C. §§ 321(e) and 331. Thus, a public pension fund would be subject to the same liability as a private citizen for a violation of the import provisions of the FFDCA.

I. Conclusion

I hope that the preceding discussion is helpful to you. From a public health standpoint, FDA is very concerned about the kind of scenario described in your letter. In our experience, many

drugs obtained from foreign sources that purport and appear to be the same as FDA-approved prescription drugs have been of unknown quality. FDA approves a drug based on scientific data submitted by the drug sponsor to demonstrate that the drug is safe and effective. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. Accordingly, the FFDCA strictly limits the types of prescription drugs that may be imported into the United States. Any state law that would legalize imports in contravention of the FFDCA would be preempted by federal law. Moreover, those importing drugs in violation of the FFDCA would be subject to liability under that statute, regardless of whether the importation was otherwise sanctioned by the state.

Nevertheless, we are aware that the high cost of some prescription drugs is a serious public health issue, and we have taken several steps in recent months to help reduce the cost of drugs in the United States without opening our borders to the potential dangers of foreign unapproved pharmaceuticals. These steps include new initiatives to accelerate approval of innovative medical procedures and drug therapies, changes to our regulations to reduce litigation that has been shown to delay unnecessarily access to more affordable generic drugs, and proposals to increase agency resources for the review and approval of generic drugs – products that are often far less expensive than brand name products and generally no more expensive in the United States than the generic drugs sold elsewhere in the industrialized world. The Administration is also working with the Congress on landmark legislation to provide a prescription drug benefit that will enable millions of America's seniors to receive coverage for their drugs in Medicare.

Thank you for your interest in this matter. If you need additional information, please feel free to contact me.

Sincerely,

William K. Hubbard
Associate Commissioner for Policy and Planning

Encl: FDA letter to the Kullman Firm (February 12, 2003)
FDA Warning Letter to Rx Depot (March 21, 2003)
FDA Warning Letter to CanadianDiscountDrugs (June 20, 2003)

Welcome to CPhA

Member Login
Home
2003 CPhA Election
CPhA Directory
Join CPhA
Bookstore
Classified Ads
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Membership
Legislative
Media
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Publications
Educational Foundation
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Frequently Asked Questions about the Importation of Foreign Medications.

Question Quick Links

How did this all start?

- Financial / Market Economies
  - World Market Economies have increased with the advent of the internet and similar technologies.
  - In Canada, medication price disparity within the U.S. is due to the national health care system and collective bargaining.

- The result is:
  - U.S. patients whose goal is "good consumerism", to seek out the lowest price alternative (*for whatever reason they might have*).
  - Storefront operations (in the US) & internet pharmacies capitalize on this pricing disparity across borders.

What is the controversy? Is it legal or illegal? Why all the confusion?

- Each state has a Board or Pharmacy that enforces state pharmacy practice laws and licenses – Pharmacies, Pharmacist, Pharm Technicians, Wholesalers.
- Food Drug Administration (FDA) enforces:
  - Food Drug Cosmetic Act - Prevents importing non-FDA approved products
  - Prescription Drug Marketing Act - Prevents RE-importing something that was originally manufactured in the US (unless you're the original manufacturer)
- Confusion has arose due to:
  - Nebulous laws that provide allowances for "personal use" in contrast to above laws. "Personal Use" has essentially been left to the discretion of customs agents.
  - False advertising
  - Politicians (combined with public opinion) that have attempted numerous times to allow this practice through legislation, only to be ruled illegal by the FDA as a result of existing laws mentioned above..
- Bottom line:
  - Until the above acts are modified, anyone that imports medications is technically breaking the law.
  - Historically, consumers have not been prosecuted.

- Board licensed wholesalers, pharmacies & pharmacists who are best able to facilitate this service are strictly prohibited, and would have their professional license revoked without question.
- Storefront businesses that are unlicensed by the boards of pharmacy are beginning to receive warning letters from the FDA to cease their activities. Despite this, more and more storefront operations open up each day.

What does everyone want? What is the common ground between patients (consumers) and the pharmacy profession?

- Want more choices for consumers with access to cheaper drugs.
- Don't want to have to break the law.
- Want the right medication (not counterfeit) at the right time (proper use).
- Want medications that do their intended purpose, free from harm.
- …based on market demand for Canadian drugs, we know that many consumers are willing to deviate from the FDA's approval rating systems for medications (knowingly & unknowingly), and all are waiving their rights by doing so.

What's the difference between foreign INTERNET pharmacies and businesses that open up brick & mortar STOREFRONTS here in the US?

- "Brick & Mortar" operations purport that they simply facilitate the importation, by providing the consumer/patient the forms and guidance to receive Canadian medications through the mail. These activities take place inside a business with an employee of the storefront.

- these employees are UN-licensed by the state board of pharmacy. They do not require any medical background whatsoever. Their interest is brokering the deal between you and the Canadian pharmacy, which pays a finders fee to the US business.
    - **Furthermore, it's the opinion of the FDA, and boards of pharmacies across the country when they engage in these activities they are acting as a pharmacy and engaging in professional pharmacy practice**.
- For the consumer, the brick & mortar storefront with a live person at a desk or behind a counter, lends a *false* sense of credibility, legitimacy, and security.
- *Keep in mind* that when you do business with these storefronts, you are asked to sign a waiver releasing them from all liability.

Where do we want to be?

- Senate – a recent measure to allow importation was approved (62-28) that will allow licensed US pharmacists & wholesalers to import prescription drugs from Canada. Yet, it requires confirmation from HHS, which is concerned with guaranteeing product quality. The HHS and the FDA has unwaveringly maintained that they can NOT guarantee the quality of all Canadian medications.
- If board licensed pharmacists and pharmacies were allowed to facilitate this importation, it would result in:
    - **Improved Safety** over what we have now with un regulated importation:
        - The FDA could develop a rating system that would differentiate agents that were suspicious or possibly lacking certain qualities, while approving some of the more common medications based on expert opinions and historical/statistical data.
            - For those medications that the FDA could not guarantee safety, it would be at the risk of those companies who decide to engage in that practice as well as "buyer beware"

just as it is NOW.
- Better control of Counterfeits (Lipitor, Epogen)
- While it might be less dangerous for patients on one drug, the potential risk for harm increases when you have multiple medications.

- Pharmacists are the most accessible health care provider and a relationship with your pharmacist is essential for proper medication management.

- **Accountability** - many of the existing pharmacy professional practice standards would continue.
- **Free Trade** - Consistent with the Bush administrations position, this would result in more choices for consumers & financially strapped seniors.
- **Price Equalization** - Eventually the market will equilibrate and prices will come down in the US, ultimately eliminating the demand for Canadian medications.

What is the ideal situation?

- **Access to reasonably priced medicine with professional clinical services from medically trained and licensed professionals that ensure it's the best medicine for you and that its working the way it should. The most expensive drug someone can buy is one that doesn't work, one they don't need, or worse one that harms you.**
- It should be MANDATED that ONLY licensed pharmacists, wholesalers, and pharmacies be permitted to engage in this activity of drug importation.
  - Pharmacists are an integral part of the medication delivery system in this country and any process that excludes the pharmacist is at risk for inappropriate medication use and severe adverse health consequences down the road.

- By allowing non-medically trained and non-licensed individuals to act on behalf of patients medical conditions ONLY for the sake of a $buck (as opposed to your health in general and proper medication use), it quickly becomes obvious that any cost savings you intended to achieve are negated by medication misadventures.

Written by S. John Johnson, PharmD

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Mary A. Dickson, Associate Executive Director (MA)

DATE: July 30, 2003

RE: Actions Against Organizations Facilitating Importation of Canadian Medications

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Attached is an updated Excel spreadsheet listing the most recent information that NABP has received from the Boards of Pharmacy concerning informal and formal actions that state, federal, and other regulatory agencies have initiated against storefronts, pharmacies, and other groups and individuals who facilitate or otherwise assist in the illegal importation of unapproved prescription medications from Canada.

Please feel free to continue providing us with additional information as it becomes available so that we can add the data to our spreadsheet and periodically provide the Boards of Pharmacy with updates.

Thank you for your assistance in compiling this table.

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary
Moira Gibbons, ELTP/VIPPS Manager
Melissa Madigan, Professional Affairs Manager

TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS

Information obtained between May 2003 - July 2003

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
AK	**7/1/03** - No actions have been initiated to date.		
AL	**3/20/03** - AL BOP filed a complaint against **Discount Drugs of Canada (DDC)** and its owner/operators, Timothy Morton & Steve Reese, in the Circuit Court of Jefferson County, seeking a temporary restraining order (TRO) as well as preliminary & permanent injunctive relief, due to allegations that it is, among other things, engaging in the unauthorized practice of pharmacy in AL. The TRO was granted by the court the same day of the filing, and the Board immediately enforced the order, shutting down DDC. **3/31/03** - Circuit Court of Jefferson County issued an order extending a previously entered TRO against DDC, until further court order. **6/30/03** - Board's request was granted and a circuit court issued a temporary restraining order against **Canadian Discount Drugs**. A hearing on the Board's request for a preliminary injunction is scheduled for July 8, 2003.	**6/03** - FDA issues warning letter to staff of **CanadianDiscountDrugs** and **Ameri-Can Global Pharmaceutical Supply, Inc**, in Ozark, AL, which assists US consumers in obtaining prescription drugs from Canada, specifically **Total Care Pharmacy** in Calgary, Alberta, CAN.	
AR	**3/03** - BOP issued a warning letter to **RxDepot/www.therxDepot.com,** Lowell, AR, a company that facilitates US consumers obtaining Canadian prescription medications.	**3/21/03 - (RxDepot/www.therxDepot.com) -** the **FDA** issued a warning letter to the company, located in Lowell, AR, notifying the firm that the agency considered the firm's operations to be illegal and a risk to public health, and in clear violation of the drug safety laws that protect Americans from unsafe drugs. FDA is also acting in conjunction with AR BOP action. **3/27/03 – FDA issued a statement** strongly supporting the filing by the OK SBOP & the OK AGO of a petition for injunction seeking to stop the **RxDepot** storefront pharmacy from violating state law. **4/10/03 -** the **Manitoba Pharmaceutical Association** in Winnipeg, Manitoba, CAN, sent a "warning letter," signed by Ronald F. Guse, BScPharm, and addressed to Derek Chan, Pharmacy Mgr of **Northgate Clinic Pharmacy,** 1410-1399 McPhillips St, Winnipeg, Manitoba, CAN. The warning letter states that **Northgate Clinic Pharmacy** must immediately cease business agreements with **RxDepot** in any state. **RxDepot** is operating in AR in violation of the state law, and they have been given direction from the State Board of Pharmacy to cease its operation.	

[Shaded areas designate new or updated information since the June 2003 report.]

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AZ	**2002-2003** - Seven (7) Canadian pharmacies applied for noresident pharmacy permits. The Board requested information on how they would comply with FDA regulations on importation. None of the applicants has responded; their applications have been deemed incomplete. **5/9/03** - AZ BOP issued a letter to the AZ Better Business Bureau asking it to warn consumers about the risks of purchasing prescription drugs illegally from Canada and other foreign countries. The letter cited the sentencing of Rory Dannenberg, operator of **Value Prescriptions** located in Phoenix, AZ, for an unrelated felony conviction. Dannenberg is one of several illegal Canadian prescription service operators being investigated by the Board for offering prescription drugs for sale without a pharmacy permit and without a licensed RPh in place.		
CA	**7/1/03** - No actions have been initiated to date.		
CO			
CT	**7/2/03** - No actions have been initiated to date.		
DC			
DE	**1/8/03** - At its January board meeting, the Board voiced its concerns and strong opposition to the importation of medications from Canada. The Board formalized its concerns in a letter encouraging NABP to oppose this activity.		
FL	**8/02** – Board denies a nonresident pharmacy license to a Canadian pharmacy: statutes require that the B4pharmacy be located in a US state. **12/02** – FL Board attorney issues legal opinion stating businesses that assist people in importing prescription medications should be treated like pharmacies because they lead to prescriptions being dispensed.		
GA		**6/03** - **FDA** issues warning letter to President/CEO of **CanadianDiscountDrugs** in Peachtree City, GA a business that assists US consumers in obtaining prescription drugs from Canada, specifically **Total Care Pharmacy** in Calgary, Alberta, CAN.	
GU			
HI	**7/03** - No actions initiated to date.	**6/03** - Pending.	
IA	**6/03** - Board sent a C&D letter to Nuway Drug.		
ID			
IL			

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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS

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IN	6/03 - Board has filed complaints with the Attorney General of IN.		
KS			
KY			
LA	9/02 - Cease and Desist Notification sent to FNC **Canadian Discount Medication** of Monroe, LA. 3/19/03 - Cease and Desist Notification sent to **Prescription Referral Services** of Monroe, LA.		
MA	7/03 - Board has been closely monitoring the issue and has been providing info to the Office of the Attorney General.		
MD			
ME			
MI			
MN	7/2/03 - No actions initiated to date.		
MO	7/2/03 - No actions initiated to date.		
MS	7/2/03 - No actions initiated to date.		
MT	3/03 – Board issued an official complaint against **RealFast Drug Store**, known as **RF Drug Store** (www.realfastdrugstore.com), located in Manitoba, CAN. **RF Drugstore** has entered into an arrange ient with Club Medz, a storefront located in Great Falls, MT. Board also intends to take **Club Medz** to court within a month if they do not comply with their order to cease and desist, and have been working with the **FDA** in hopes of obtaining the involvement as well. 4/03 – Board investigated **Club Medz**, issued a subpoena, and **Club Medz** ceased operations at the end of the business day on 4/10/03. Board had charged that the lay people manning the storefront were engaged in the unlicensed practice of pharmacy and that they were aiding and abetting an illegal act. 4/03 - Board issued a complaint against **Real Fast Drugstore** (aka **R.F. Drugstore**) with the Manitoba Pharmaceutical Association. The matter is still under MPA's consideration.		

[Shaded areas designate new or updated information since the June 2003 report.]

TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS

Information obtained between May 2003 - July 2003

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
MT	**Spring '03** - Several C&D letters sent to Canadian mail order pharmacies. **5/03** - Denied an out-of-state mail service pharmacy license to Canadian pharmacy on grounds that the Board is unable to license an entity to perform an illegal act. **5/03** - Contacted both a RPh & a layperson seeking to open storefront operations, counseling the RPh not to aid and abet illegal activity or face disciplinary action. The layperson was told that the Board would consider her to be engaged in the unlicensed practice of pharmacy and aiding and abetting an illegal act. So far, neither operation has begun. **6/03** - Began action against a new **Rx Depot** in Billings, MT, and will follow the same rationale as previously used in the **Club Medz** case. Informed the FDA of the situation via phone. **6/03** - Issued a C&D letter to the Billings Gazette, a state newspaper running a full-page ad for **Canada Discount Rx**, on the grounds that they are aiding and abetting an illegal act. The ad appeared in the June 18, 2003 issue. **7/31/03** - Board filed a petition in district court seeking injunctive relief against **Sandra S. Kennedy d/b/a Rx Depot.** The Board seeks a temporary restraining order barring **Kennedy/Rx Depot** from conducting any type of "prescription service," among other things.		
NC	**6/11/03** - the NC BOP announced the issuance of Cease & Desist Orders for 5 businesses that are forwarding prescriptions to Canada to be filled and returned to the US. Orders were sent to: **Discount Drugs of Canada**, Gastonia NC; **Canada Drug Outlet, Inc**, Concord, NC; **Rx Price is Right, Inc**, Winston-Salem, NC; **Canada Drugs**, Asheboro, NC; and **Prescription Care of NC**, Banner Elk, NC. **7/14/03** - Per Carlson Carmichael, lawyer for the NC BOP, as of mid-June 2003, they have sent C&Ds to 6 locations in NC that are storefront-type operations. They are close to taking the next step, although the Board needs to give the final approval, which would be an action or actions for injunction in court against the locations.	**7/1/03 - FDA** issues a letter supporting the Board's efforts to stop businesses that forward prescriptions to Canada to be filled by Canadian pharmacies for U.S. consumers, and the FDA offers its assistance in the Board's efforts to stop such businesses.	

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Information obtained between May 2003 - July 2003

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ND	**Fall 2002** – BOP has sent numerous cease and desist orders to Canadian and other international pharmacies that ship into ND.		
NE			
NH	**7/2/03** - No actions initiated to date.		
NJ			**5/12/03** - New Jersey Legislature bill No. 570 Section 34 (b) addressing pharmacists was amended to prohibit the shipping of Canadian and unapproved meds to NJ. **5/22/03** - amendment prohibiting the shipment of Canadian/unapproved meds was dropped.
NM			
NV			**5/03** - Law enacted making it unlawful to fill prescriptions via the Internet, using illegally imported medications, or to assist one in doing so.
NY	**7/03/03** - Investigations have been initiated.		
OH	**11/00** – Cease and desist order issued against **Provincial Pharmacy, Inc**, in Windsor, Ontario, CAN. Basis: unlicensed shipping of prescriptions to OH residents.		
OK	**3/27/03** – The state authorities filed a petition in OK state court alleging that **RxDepot** is illegally operating an unlicensed pharmacy. **6/3/03** - State court granted a temporary restraining order against **RxDepot** which becomes effective on approximately 8/31/03 so that **RxDepot** may appeal the order. Judge's order stated **RxDepot** violated state statutes.	**4/10/03** - the **Manitoba Pharmaceutical Association (MPA)** in Winnipeg, Manitoba, CAN, sent a "warning letter," signed by Ronald F. Guse, BScPharm, and addressed to Derek Chan, Pharmacy Mgr of **Northgate Clinic Pharmacy**, 1410-1399 McPhillips St, Winnipeg, Manitoba, CAN. The MPA received a copy of the court document filed in the District Court of OK (case # CJ-2003-2643) describing the conduct of **RxDepot** in the state of OK being in violation of state law. The warning letter states that **Northgate Clinic Pharmacy** must immediately cease business agreements with **RxDepot** in any state and the shipment of medication into the state of OK.	
OR	**7/2/03** - No actions have been initiated to date; however, the Board has ongoing investigations.		
PA			
PR			

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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS

Information obtained between May 2003 - July 2003

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
RI	**2002-** Cease and desist order sent to two Manitoba pharmacies. Complaint sent to MB pharmacy regulators regarding MB pharmacies shipping to RI.		**2/03** – Legislation introduced to **allow** Canadian pharmacies to ship prescription meds to RI. Legislation, backed by RI Medical Society, would allow BOP to license CAN pharmacies. BOP ED Cordy said Board would oppose the bill.
SC			
SD	**2002-2003** – Board has sent cease and desist letters and has phoned Canadian pharmacies to inform them of their illegal shipping of meds into SD. **2002-2003** – Complaint sent to MB pharmacy regulator concerning MB pharmacies shipping to SD residents.		
TN	**10/02** – State sent cease and desist order to **CanadaDiscountRx**. **1/03** - C&D letter sent to **Canadian Rx Consultants Group**, Maitland, FL. No response. **3/03** - C&D letter sent to **Canadian Drugs2U**, Nashville, TN. No response yet; Board is considering next action. **4/03** - C&D letter sent to **Global Pharmacy Rx**, Cookeville, TN. Owner advises that they are no longer in business. **5/03** - Board decides that facilitating the importation of Rxs for Canadian pharmacies is the practice of pharmacy and storefronts should be licensed. **5/03** - C&D letter sent to **Medi Save**, Knoxville, TN. Attorney for the owners of **Medi Save** advises that they are no longer in business. **5/03** - C&D letter sent to **RealFast** of Winnipeg, Manitoba, CAN. **6/03** - C&D letter sent to **Canada Direct Pharmacy, LTD**, in Calgary, Alberta, CAN. No response.		

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Information obtained between May 2003 - July 2003

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
TX	7/03 - The Board will send C&D letters to any facilitators who receive or process prescriptions, and any person or business that uses the word "pharmacy," or graphical representations of the same. 7/3/03 - TX SBOP mailed nine (9) C&D letters. A 10th C&D letter will be mailed soon.		
UT	7/02 - C&D Order issued to **Rx North America.** 4/03 - C&D Order issued to **Discount Prescription Service**, a facilitator. 4/03 - Complaint filed with the **College of Pharmacists of British Columbia** against a BC pharmacy that appeared to be shipping prescriptions into UT. 4/03 - Complaint filed with the **College of Physicians and Surgeons of British Columbia** against a doctor allegedly prescribing medications for export to UT.		
VA			
VI			
VT	Foreign Prescription Drugs" is published in the Vermont Board of Pharmacy Newsletter. 7/03 - The Board currently has two (2) investigations open regarding Canadian internet pharmacies. The allegations are: one is a storefront, the only one believed to be in VT; and the second involves a firm that has come to VT, advertised a "Canadian Drug" seminar, and had a pharmacist representing the company at the conference. Both investigations are still open.		VT has new rules in the legislative process, slated to go into effect **8/1/03**. In the new rules, any pharmacy that ships meds into VT must be licensed by the state and have one RPh licensed in VT.
WA	Several letters have been sent advising Canadian pharmacies not to ship to residents of WA.		
WI	7/7/03 - There is one case pending which is against **Philip D. Kuehnl** and **Premium Discount Pharmaceutical Services.**		
WV	5/13/03 - Cease and desist letter sent to **Discount Prescription Center of WV**, a storefront. **Discount Prescription Center** filed an action in court to bar authorities from closing it, claiming it is not a pharmacy.		

[Shaded areas designate new or updated information since the June 2003 report.]

TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS

Information obtained between May 2003 - July 2003

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
WY	6/3/03 - Board sent cease and desist letter to **Canada Direct Pharmacy** in Calgary, Alberta, CAN, which sent advertising to St Anthony Manor. 7/03 - Board sent a cease and desist letter to **ThriftMedsNow Pharmacy** in Manitoba, CAN, due to its being an unlicensed pharmacy that is advertising in a Wyoming paper.		
	FEDERAL ACTIONS		
	FDA - Cyber Warning Letters to Canadian Pharmacies		
	10/31/01 - www.RxNorth.com; www.OnlineCanadianDrugstore.com (MediPlan)		
	10/31/01 – www.Canadameds.com (Point Douglas Pharmacy)		
	11/15/01 – www.Canadarx.net (Target Zone)		
	ACTIONS TAKEN BY CANADIAN REGULATORY AGENCIES		
	May 2002 - The **Ontario College of Pharmacists**, the regulatory body for enforcing pharmacy practice standards, charged **The Canadian Drugstore, Inc**, with 15 different violations, including operating an unlicensed Internet pharmacy without registered pharmacists from November 2001 to February 2002.		
	March 2003 – Cross-Border Statement was issued by **Nova Scotia College of Pharmacists** stating, among other things, that Nova Scotia pharmacists and pharmacies should not participate in any scheme or service to accommodate importation of Canadian medications by US citizens. Pharmacists/pharmacies that accommodate such services may be found to be practicing unethically and may be found guilty of professional misconduct.		
	April 2003 – Canadian Broadcasting Corporation (CBC), Fredericton – The **New Brunswick College of Physicians** has suspended the license of **Dr Andre Loiselle**, a physician accused of helping to sell prescription drugs over the Internet. **Dr Loiselle** wrote prescriptions for a Web site that markets drugs to senior citizens in the US, even though he		
	April 2003 - The **Manitoba Pharmaceutical Association (MPA)** in Winnipeg, Manitoba, CAN sent a "warning letter" to **Derek Chan**, Pharmacy Mgr of **Northgate Clinic Pharmacy.** The warning letter states that Northgate Clinic Pharmacy must immediately cease business agreement with **RxDepot** in any state and the shipment of medication into the state of OK.		

[Shaded areas designate new or updated information since the June 2003 report.]

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation

ACTIONS TAKEN BY CANADIAN REGULATORY AGENCIES, CONTINUED

July 2003 - The **Ontario College of Pharmacists (OCP)** resolved its prosecution against **The Canadian Drugstore Inc; Rep-Pharm, Inc; Stephen Bederman, RPh**; and **Dr Stanley Gore** and his company **Canadian Custom Prescriptives, Inc.** Summary of charges involved: unlawful dispensing or selling of a drug to a patient; operating an unlicensed pharmacy; and dispensing a prescription without written authorization of a Canadian doctor. The specific judgments follow:

- **The Canadian Drugstore, Inc,** pled guilty on 6/23/03 to one offense contrary to the Regulated Health Profession Act, 1991 (RHPA), and four charges contrary to the Drug & Pharmacies Regulation Act (DPRA).
The Ontario Court of Justice fined the company (**Canadian Drugstore, Inc**) $20,000. This fine amount was part of an overall disposition that included a $125,000 payment by the **Canadian Drugstore, Inc,** to the Leslie Dan Faculty of Pharmacy, University of Toronto, to establish the Ontario College of Pharmacists' Professorship in Pharmacy Practice.
- **Rep-Pharm** was fined $5,000.
- Charges against the **RPh Bederman, Dr Gore**, and affiliated companies were dropped; however, the pharmacist faces a disciplinary hearing in December 2003, and the doctor was referred to the College of Physicians and Surgeons of Ontario for a hearing and determination.

[Shaded areas designate new or updated information since the June 2003 report.]

Attachment B

Attachment C

A Revolving Door

Gaining Riches From the Market's Flaws

By Mary Pat Flaherty and Gilbert M. Gaul
Washington Post Staff Writers
Saturday, October 18, 2003; 3:15 PM

If Marty Rubin had realized his ambition of pitching in the big leagues, he might not have turned to fraud -- at least in the view of one of Rubin's attorneys.

Rubin was born in Brooklyn, and "baseball was Martin's life," the attorney said. From "neighborhood stickball games," Rubin advanced to local leagues until finally moving to California "to try out for the Angels. The tryout went poorly and Martin was forced to think of other job options," the attorney wrote.

Rubin bought a drugstore but eventually shifted into a much more lucrative business. He set up fraudulent pharmacies that ordered discounted medications and resold them at a markup across the country. With the profits, Rubin financed a high life: houses in Southern California

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and Las Vegas, a condo in Puerto Vallarta, Mexico, and heavy gambling at casinos.

Three times since 1989, he has struck out in federal court and been imprisoned for drug scams. Rubin, 53, is finishing a five-year sentence in Long Beach, Calif. Drug manufacturers lost more than $12 million to Rubin as he fed truckloads of medications into the shadow market, court records show.

Court records from the past 15 years present him as a master at probing weaknesses in the drug distribution system. He always apologized when he got caught.

"I apologize and will never do it again," Rubin told a judge during his first case in Phoenix.

Yet while his jury trial in Arizona was in progress, he was already involved in deals that would lead to his conviction in 1992 for the same type of fraud in Kansas City, Mo., court files there show.

The Arizona judge was not pleased to learn of the Kansas City case.

"Judgment might suggest you back off a little once indicted," the Arizona judge told Rubin. His attorney said Rubin thought he was in a legal business. Rubin was "not an armed robber," the attorney said.

"He would have gotten less money," the judge retorted, according to a transcript.

Rubin's attorney said his client had seen the error of his ways "with some assistance from the jury and court."

Rubin ended up testifying for the government in the case in Kansas City. He was imprisoned until 1994 and faced a long probation. In seeking to end the probation, Rubin's attorney told the court that Rubin was "a consultant to the

prescriptions.

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pharmaceutical industry," where "part of his job is to educate others about the perils of criminal conduct."

But soon Rubin was in trouble again.

While still on probation in the Kansas City case, he was running a "one-man" consulting firm in Los Angeles "in order to disguise my involvement in the scheme and thereby conceal my prior fraud convictions from pharmaceutical manufacturers," he later admitted in court. He "masterminded" the creation of a network to once again cheat drugmakers and resell medications, he acknowledged, becoming a "silent partner" and controlling "much of the day-to-day operations."

In 1999, Rubin was indicted in Los Angeles after New Mexico pharmacy inspectors were tipped about an Albuquerque pharmacy called Blue Skies that was buying large quantities of discounted medicines ostensibly for nursing homes, hospices and HIV clinics.

David Villegas, the purchasing agent for Blue Skies, testified that he had no experience and set up the business at Rubin's behest but was told by Rubin never to disclose Rubin's role. An ex-convict, Villegas said Rubin gave him $7,000 to find a warehouse for the start-up. Villegas kept a separate phone line in the business "that was only to be used to talk with Rubin." Villegas told the court he traveled every third Saturday to Las Vegas to report to Rubin.

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Drugs in Short Supply

Higher Prices, More Compromises

By Mary Pat Flaherty and Gilbert M. Gaul
Washington Post Staff Writers
Sunday, October 19, 2003; Page A16

The faxes, e-mails and phone calls come in every morning to hospitals across the country, touting hard-to-find medications that small wholesalers have ready for sale -- at dramatically marked-up prices.

Medications in short supply from major wholesalers are pitched on those sales calls, confounding and enraging many hospital pharmacy managers who say they are held hostage to price-gougers.

The scramble for suddenly scarce drugs exposes patients to increased risk of medication errors, pharmacists said. When hospitals must use substitutes for their usual drugs, "it affects the quality of patient care in a huge way," said Rita Shane, pharmacy director for the vast Cedars-Sinai Medical Center in Los Angeles.

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The small wholesalers offer everything from workhorse drugs to combat infections and nausea to lifesaving drugs for managing premature births and spinal injuries. The drugs are hawked at double or triple the usual price, dozens of solicitations obtained by The Washington Post show.

"It's a vile business practice," said Alyce Holmes, pharmacy director for the 101-bed Betsy Johnson Regional Hospital in Dunn, N.C.

Shortages often hit without warning, for reasons as varied as drops in raw materials, production delays, unexpected demand and phase-outs of brand-name drugs as cheaper generics enter the market.

"You open your order and look in the box, and what you wanted isn't there," said Tamra Kaplan, pharmacy director at Anaheim (Calif.) Memorial Medical Center. "That's one way you find out. It's even more aggravating when the first indication you get are the calls from these gray-marketers."

Anaheim has booked surgeries around its supply of Solu-Medrol, an anti-inflammatory. Earlier this year, it rationed the antifungal drug amphotericin B after it increased from $6 to $31 a vial.

When production of the snakebite treatment CroFab lagged last year, the price for a two-vial carton went from $1,720 to as much as $5,000. The average patient needs 20 vials. Some hospitals had to turn to veterinary drugs and medications from zoos, said Leslie Boyer, medical director of the Arizona Poison and Drug Information Center in Tucson.

When hydrocortisone supplies dropped and prices soared earlier this year, Cedars-Sinai scoured its 850-bed facility for every bit of the drug, a mainstay to treat severe allergic reactions. "It is absurd and perverse to me that something like flu vaccine or the drugs our anesthesiologists need can

prescriptions.

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be out of supply from our usual, major wholesaler yet be available from very small secondary wholesalers," Shane said.

To avoid the small wholesalers, the hospital spent $250,000 in 2002 on expensive substitute drugs. "Sometimes we have six or eight people working all day to find a supplier we know because we don't deal with small wholesalers," said Ron Reinhart, a pharmacy buyer for Cedars-Sinai. "We've been a bit fearful of where they buy their product from."

At times, when urgent needs arise, there is no avoiding small wholesalers. "I try to keep up on who is who, and we look very closely at dating and packaging when it comes in," said Doris S. Craft, chief pharmacist at the 100-bed Wilson (N.C.) Medical Center. "But sometimes you're buying on faith that it's good and on the up-and-up because you have to have it."

Desperate for Solu-Medrol, Craft ordered with small suppliers who had approached her through faxes, paying $358 on July 11 and $263 on July 14 for the same amount of the drug, which is as much a staple to a hospital as milk is to a household. Two weeks later, she was able to buy from her regular wholesaler -- Cardinal Health Inc., one of the nation's biggest distributors -- for about $74.

"I don't care what they say about being smart business people, and knowing the marketplace and supply and demand," Craft said. "If I have to pay four or five times my usual price to get something my patients can't do without, then I'm being gouged."

In a letter to Craft, the wholesaler who charged her $358 wrote that providing hard-to-find drugs on short notice involved "a lot of legwork" and significant costs. "Our company is proud to be part of the healthcare delivery system and, in our view, we do not deserve a pejorative label like 'price gouger,' " wrote Trevor Yankoff, president

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of Zylex Pharmaceuticals of San Clemente, Calif. "If the price is too high we would recommend not buying from us."

Some small wholesalers say they build inventories by stocking medications nearing their expiration dates that other wholesalers need to sell quickly. Others take advantage of regional variations in supply. Still others pay painstaking attention to market forces that may cause drugmakers to alter production.

But other small wholesalers have obtained medications under less reputable circumstances.

During the shortage-plagued 2000 flu season, a New Jersey wholesaler bought steeply discounted vaccine for nursing home patients and pledged not to sell the drug on the open market. The wholesaler violated that contract, according to Food and Drug Administration records released under the Freedom of Information Act. The records show the wholesaler sold nearly half of the 15,000 doses it had purchased at $23.65 each to a wholesaler in Savannah, Ga., for $93, who sold to a Miami wholesaler for $95, who sold to various hospitals and clinics, charging $130 to two in New Jersey and $147 to one in Pittsburgh. That chain of sales took fewer than 11 days, the records show.

A General Accounting Office report found that wholesalers ignored pre-booked orders to sell to "the highest bidders." Hawaii's state health system ordered 12,000 flu vaccine doses at $2.80 in May, well before the outbreak. But its distributor cut the order, and the state had to pay double to other suppliers in September.

Shortages have risen since 2000 and are lengthening, according to a Web site for hospital pharmacy buyers maintained by the University of Utah.

From about 20 drugs per year before 1999, the list

expanded to 80 in 2001 before dropping back to 39 last year -- but those shortages were more persistent.

As shortages rise so do the pitches from wholesalers, some hand-scrawled, some promising to "find anything you need" and loaded with exclamation marks.

"I even had one offer me a coffee mug," Holmes said.

A Family Affair

Father Leads Clan to Drug Sale Riches -- and Prison

By Mary Pat Flaherty and Gilbert M. Gaul
Washington Post Staff Writers
Sunday, October 19, 2003; Page A17

At first blush, Robert J. Fenton seems an unlikely criminal. Rotund and bearded, the 70-year-old patriarch bears a striking resemblance to Santa Claus. Married in Flushing, N.Y., in 1954, Fenton and his wife, Irene, eventually migrated to Las Vegas, where they opened a pharmaceutical wholesaling company. Their sons and daughters took up the business until the family's reach extended deep into the West and Midwest.

The Fenton clan ran or controlled a web of corporations and pharmacies that bought and sold drugs in the shadow market in pharmaceuticals, passing medications stored in unknowable conditions through an untraceable network, according to numerous court filings. Over the past decade, they bilked drugmakers out of at least $16 million.

Some of Fenton's children ran their own operations, recruiting teams of front

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men, relying on sophisticated computer programs to track their drug sales and amassing great wealth, investigators found.

The greatest fortune was that of Fenton's daughter Wendy E. Fenton Almanza and her husband, Darin D. Asay, who ran their operations out of a $6 million 12,000-square-foot house in Evergreen, Colo., with 11 bathrooms, a heated outdoor deck, gold leaf in a vestibule, hand-glazed walls, a home theater and a view of the Continental Divide. Still in their thirties, the couple traveled in a Land Rover, a Lamborghini Diablo and their own Beechcraft jet.

Almanza and Asay ordered pharmaceuticals through closed-door pharmacies that they owned or controlled throughout the West. The pharmacies are supposed to serve only nursing homes and hospices, in return for which they receive discounts from drugmakers of as much as 80 percent. The pharmacies sign contracts promising not to sell the drugs in the open market. Almanza claimed to be supplying 1,320 nursing home beds in Golden, Colo. The beds did not exist, her plea agreement shows.

Instead, she and Asay sold those drugs to 12 other wholesalers from New York to California.

The ruse of ordering truckloads of medication for nonexistent customers exploits a regulatory gap. Many state licensing agencies do not distinguish between closed-door and retail pharmacies and are unaware of how many closed-

prescriptions.

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door pharmacies they have. Few drug manufacturers verify the number of nursing home beds that the pharmacies claim to serve.

A tipster exposed Almanza and Asay's operation. Searches in an office above the couple's three-car garage revealed the threat they posed to consumers: recall notices for pharmaceuticals long gone out the door.

Almanza and her husband pleaded guilty in 2000 to mail fraud for opening "at least" eight closed-door pharmacies in six states and cheating 17 pharmaceutical companies out of $9.4 million. Asay was sentenced to 78 months in prison. Almanza received 33 months. She agreed to cooperate with investigators to reduce her prison time. Almanza and Asay declined to be interviewed.

She retrieved computer files and boxes from her parents' home in Las Vegas that showed how the family hid assets, according to her sentencing hearing. Before 2002 ended, Almanza's parents and brother Thomas were in court facing charges of defrauding pharmaceutical makers.

In July 2002, after 17 years in business, the Fentons' Las Vegas wholesaling company, Frontier Pharmaceutical Distributors, relinquished its license to Nevada authorities.

Last month, the family patriarch, Robert Fenton, was sentenced for mail fraud in Cleveland. He was found guilty of handling drugs that had been solicited by a telephone boiler-room operation that randomly called Ohio pharmacists listed in the Yellow Pages and asked if they wanted to make extra money selling off their excess product, court records show. Charges against his wife were dropped.

Fenton received a fine and probation. Prosecutors characterized it as "forced retirement" from the wholesaling business.

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But he continues to work, from what he told the court. His wife employs him in a CPR training center she operates in Las Vegas.

The Straw Man

Salesman Fell Into a Shadow Market

By Mary Pat Flaherty and Gilbert M. Gaul
Washington Post Staff Writers
Sunday, October 19, 2003; Page A17

Sam Whatley Jr., a salesman for a Baltimore pharmaceutical distributor, scoured the list of licensed drug wholesalers in Florida. For a salesman who relied on cold calls, the list was an opportunity: If he made a big sale or landed a new account, the commission could help him top his best-earning year of $26,000.

Florida had 1,399 wholesalers -- a big pool. Whatley turned to the A listings and started dialing.

He hit pay dirt in the B's. BTC Wholesale LLC of Kissimmee, Fla., placed its first order and said it wanted to keep doing business. For Whatley, 48, that call last year was blind luck -- until it proved bad luck.

Through BTC, Whatley was lured to run a firm in Odenton, Md., that is now alleged to be one of several shell companies in a multimillion-dollar fraud operation. The operation sold hundreds of thousands of doses of

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medications that were diluted, stolen, relabeled or illegally imported, a Florida indictment states. The drugs were stored in everything from duffel bags to car trunks.

Whatley, who has not been charged, said he thought he was throwing in with reputable and rich men who could help secure his future.

"I know I've been called a straw man, and I guess that's about right. I'm learning I was very, very naive," he said. "I swear to you, if I had known these guys were out there peddling false and diluted stuff, I wouldn't have had anything to do with it."

The man behind the fraud was Michael Carlow, according to the indictment filed in Fort Lauderdale, Fla., in July against Carlow and 17 co-conspirators. Despite a 1973 robbery conviction, Carlow, 51, managed to obtain a pharmaceutical wholesaler's license. In 2000, he lost that license after he was caught loading $83,000 worth of the chemotherapy drug Neupogen from a car trunk into his van in a Miami parking lot midafternoon in June. Neupogen requires refrigeration and is not supposed to be shaken.

Carlow received probation, yet by the time of the July indictment he was at the hub of at least 12 pharmaceutical wholesaling operations in seven states, prosecutors say. The licenses were in the names of Carlow associates and relatives. Investigators contend that many of the drugs came from suspicious sources and flowed into the laundry room and garage of Carlow's $1.3 million home in the

prescriptions.

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gated community of Weston, Fla.

Carlow's attorney, John Howes, said, "The state has far-fetched ideas about what happened and doesn't have the hard evidence and proof to establish what they say."

When Whatley called BTC, he spoke with Thomas Atkins Jr., Carlow's brother-in-law. Whatley said the two men soon offered him a job, sending him an express mail letter with plane tickets to Florida and beachfront reservations in Fort Lauderdale.

During his nearly 30 years as a pharmacy technician and in sales, Whatley said in an interview, "nobody had ever sent me anywhere, never flown me anywhere. These guys were first class." To Whatley, Carlow's house "was like a castle. Classy, grand. And Michael is a short, dumpy guy like me who seemed to have gotten fortunate. I saw myself getting there."

Carlow or his wife owned a yellow $87,000 Dodge Viper, a $249,000 Ferrari convertible and a 36-foot Sea Ray boat named "Delicious," investigators said.

Whatley's first step was a $30,000-a-year sales job plus commission with G&K Pharma, a licensed pharmaceutical wholesaler in a strip mall on Piney Orchard Parkway in Odenton. Whatley helped open the business, and Atkins was president. Whatley later said he thought the business was selling pharmaceuticals obtained from other legitimate wholesalers and drug manufacturers.

"I was really trying to make something of it," he said.

He landed a few new accounts. But then Atkins and Carlow told him all he needed to do was check the mail and pick up an occasional package, Whatley said. G&K was merely a front, one of the licensed companies Carlow needed for an appearance of legitimacy, the indictment and investigator

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records allege.

According to an account he gave to investigators and The Washington Post, Whatley's job became hawking pharmaceuticals that Atkins and Carlow had in Florida. But the drugs' pedigree papers -- records that are supposed to allow every drug sale to be tracked -- showed the Florida drugs coming out of Maryland.

Whatley said the discrepancy "didn't make red flags go off for me, because this was only my second wholesale job. I was just getting my feet wet when I went to G&K."

A shipment of counterfeit drugs finally brought the operation down.

On Sept. 27, 2002, Whatley received Procrit in an overnight package. He later recalled that it "looked just perfect, right off the factory line." The boxes of the injectable drug, which fights fatigue in HIV and cancer patients, had the 3-D watermark on the label and the anti-tampering seal in place.

It was, investigators later acknowledged, very good counterfeit.

Kevin Kulik, Atkins's attorney, said his client did not know that some of the product may have been doctored.

Whatley sent out feelers for buyers, including to a middleman in Miami he had met through Carlow and Atkins. From a drugstore on Miami's North Flagler Street, there was a nibble.

At going rates, a box of the high-strength Procrit was selling for $1,731. The price offered the drugstore: $1,693. Before he agreed to the deal, the pharmacist asked to see the drug's pedigree paperwork. He became suspicious because the papers appeared to be boilerplate and did not seem to match the order.

He alerted state investigators to the offer. At their behest, the sale was arranged for 129 boxes of Procrit for $218,397.

When the middleman arrived, the drugs were seized. The pedigree papers -- claiming the drug had moved from Ohio to Maryland to Indiana and then Miami -- were false, investigators said. Many of the boxes also contained only one-twentieth of the strength on the label, making them counterfeits, investigators said in a search warrant affidavit.

Whatley was at a grocery store on Oct. 1, 2002, when he received a cell phone call. Federal agents working with Florida authorities wanted to meet him. They told him that the shipment had been seized and that it was counterfeit. He agreed to cooperate. Two weeks later, Whatley received a termination letter from Atkins: G&K was suffering financially and no longer needed his services.

washingtonpost.com

Internet Trafficking in Narcotics Has Surged

By Gilbert M. Gaul and Mary Pat Flaherty
Washington Post Staff Writers
Monday, October 20, 2003; Page A01

Second of five articles

LAS VEGAS -- In July 2001, regulators at the Nevada State Board of Pharmacy noticed something unusual among the reams of data that flow into the busy agency each day. Buried along with the other numbers was a report from a small Internet pharmacy that had filled 1,105 prescriptions for painkillers and other dangerous drugs that month.

The same tiny pharmacy had dispensed just 17 prescriptions in the prior six months.

Virtually overnight, prescriptiononline.com had become one of the largest distributors of controlled substances in Nevada. Over the next year, the online pharmacy shipped nearly 5 million doses of highly addictive drugs to customers scattered across the country. By the time regulators shut the Las Vegas firm in January, prescriptiononline.com accounted for 10 percent of all hydrocodone sold in Nevada, regulators said.

It turned out that the booming business was owned by a 23-year-old former restaurant hostess. But it was run by her father, who had been convicted of a felony in 1992.

"For any single pharmacy to account for 10 percent of any drug is incredible," said Louis Ling, general counsel to the Nevada pharmacy board. "The fact that it was a highly addictive painkiller and an Internet site run by a convicted felon was even more troubling. This was unlike anything we had ever seen."

With little notice or meaningful oversight, the Internet has become a pipeline for narcotics and other deadly drugs. Customers can pick from a vast array of painkillers, antidepressants, stimulants and steroids with few controls and virtually no medical monitoring.

There are dozens of legitimate online drugstores and mail-order pharmacies. Unlike rogue sites, they require customers to mail in prescriptions from their doctors. Typically, the legitimate sites offer a full range of medications, with painkillers accounting for less than 20 percent of their business.

In contrast, a majority of the rogue sites' sales are for hydrocodone, Xanax, Valium and a few other addictive drugs. Many work with middlemen who set up the sites' customers with doctors who are veritable script-writing machines. Some of those doctors have financial problems and histories of substance abuse or medical incompetence, records show.

The online merchants now feed a sprawling shadow market for prescription drugs, frustrating medical leaders alarmed by the threat to public health and investigators hard-pressed to keep up with nimble Web sites that can open and close at a moment's notice.

"It's like rabbits," said Wayne A. Michaels, a senior investigator for the Drug Enforcement Administration. "Every day, there are more of them. They're up, they're down, they're foreign, they're domestic."

The agency recently created a six-person task force solely to track the online trade in narcotics. But officials acknowledged the effort is a form of "triage" amid an escalating crisis. "We're afraid it's going to overwhelm us, once we've identified all these sites," said Elizabeth A. Willis, chief of the DEA's drug operations section.

The multimillion-dollar industry has appeared overnight, pumping millions of pills into some of America's smallest and most economically distressed communities.

The Washington Post obtained and analyzed a Nevada pharmacy board database of 30,000 orders filled by prescriptiononline.com. The analysis found that four of every 10 pills poured into four southern states with widely documented prescription-abuse problems. A disproportionate share of those drugs went to customers in small towns.

Some small Tennessee towns received 50 times more painkillers per capita than large cities, the analysis found. For example, Church Hill got 1,013 pills for every 1,000 residents; Nashville, just 26. Bristol got 1,584; Memphis, 14.

"It's a no-brainer why you see high volumes in these little places," said Tammy Meade, a narcotics prosecutor in Nashville. "Users and people who want to get their hands on enough to distribute can't doctor shop in places like that. And if they use the Internet, someone like me . . . is going to have a tougher time finding out."

Stretching from Florida to California, the Internet pipeline has left a trail of deaths, overdoses, addictions and emotionally devastated families.

"It absolutely blew my mind that you could get these drugs online," said Sue R. Townsend, the coroner in Aiken County, S.C. Her son Douglas, 30, died after driving his car into a fence in September 2001. His family said he had taken a generic form of the tranquilizer Xanax, which they said he had purchased from myprivatedoc.com, a now-defunct Web site in Mesa, Ariz. Townsend's family sued the Web site, the pharmacy and the Arizona doctor who wrote the prescription, accusing them of selling the drug without a proper medical consultation. The case was recently settled with no admission of liability.

"Losing Doug has broken our hearts," Sue Townsend said, fighting back tears. "He had a young wife and a baby boy who will never know his daddy. Somehow we have to tell how dangerous this is, because it's happening all over."

In a typical purchase from a rogue site, a customer logs on and orders hydrocodone (generic Vicodin and Lortab). The Web site steers him to a middleman, often another Web site, which arranges a telephone consultation with a doctor. The customer and the doctor talk briefly, after which the doctor writes the prescription and sends it electronically to the Internet pharmacy. The pharmacy ships 60 pills to the customer by overnight mail. Total cost: $290. The pharmacy pockets $190 for the hydrocodone and the doctor and the middleman split the remaining $100 as a consultation fee. There are no face-to-face meetings, lab tests, X-rays or follow-ups.

There are dozens of Web sites selling narcotics in the United States, with scores more operating offshore. Federal prosecutors have shut Web sites, filed indictments and won guilty pleas from several owners. But it often takes years to prove a case. In the meantime, the pills move.

For each site closed, "two or three more open," said Jennifer Bolen, a former federal prosecutor in Knoxville, Tenn. "It is so easy for them to close down a site one day and open a new one the next."

For the DEA, an agency already responsible for everything from drug cartels to street drugs, trying to police the growing number of online pharmacies "is like trying to work every corner drug dealer," said Laura M. Nagel, the agency's deputy assistant administrator. "We can't do it all."

When prosecutors shut the Internet pharmacy operations at thepillbox.com in San Antonio, much of the business shifted to prescriptiononline.com in Las Vegas, records show. When that site was closed two years later, Nevada regulators suspect the business shifted yet again -- this time to Florida.

Some Web sites have dozens or even hundreds of affiliate sites. Others are designed to appear as though they are headquartered in the United States when they are really offshore, in such places as Namibia, Thailand and Sri Lanka. The growing numbers of foreign online pharmacies operate with near impunity. The Food and Drug Administration's strongest recourse is to send a warning letter, which usually is ignored.

"As an investigator, it's incredibly frustrating," said Robert J. West, a special agent with the FDA's Office of Criminal Investigations. "All we can do is bang away and try to draw attention to what these guys are doing. Right now, I don't think people have any idea how widespread or dangerous this is."

Little Regulation

States regulate pharmacies, creating widely different rules governing Internet sites. Under-staffed pharmacy boards barely have time to inspect brick-and-mortar pharmacies, let alone virtual ones. Many online pharmacies have ignored state efforts to register them. Only one state -- California -- has a full-time agent investigating doctors writing prescriptions for Internet pharmacies.

The lax oversight comes amid Congress's inability to pass legislation requiring even minimal disclosure by Internet pharmacies.

In 1999, then-Rep. Ron Klink (D-Pa.) issued a warning at a committee hearing: "I am concerned a 'Wild West' world is unfolding before us, where many consumers are accessing potentially dangerous drugs with little or no practical guidance. Yet because it is e-commerce, there is a mentality: It must be progress."

In 2000, the FDA, the General Accounting Office and several House members urged that online pharmacies be required to disclose their owners, locations, doctors, affiliated pharmacies and telephone numbers. But Congress never followed through. Nearly four years later, there is still no disclosure requirement.

"Getting a bill regulating the Internet is about as hard as it gets," said William K. Hubbard, the FDA's senior associate commissioner. "You have all of these people worrying about stifling this wonderful thing . . . and they don't want the bad Feds in there."

A Post reporter sent e-mail asking for identifying information to 15 online pharmacies specializing in painkillers. Only one responded. It declined to say who owns the site or where it is located. One online pharmacy included a telephone number for customer service that linked to a freight forwarding company in Miami. When a reporter called, a secretary said that it moved shipments for a customer in Costa Rica.

In late 1999, the National Association of Boards of Pharmacy instituted a voluntary system for certifying online pharmacies, including inspections and disclosure. But of the hundreds of Internet pharmacies now operating, only a "dozen or so" signed up, said Carmen Catizone, the board's executive

director. Most of those are large, legitimate sites, such as drugstore.com.

One pharmacy that received certification was prescriptiononline.com. "I can't explain what happened there," Catizone said. "I know we certified it originally, and then later on we got some complaints, and we suspended their certification. Obviously, if we knew then what we do now, we never would have certified them."

Easy Licenses

Regulators in Nevada faced a similar situation in April 1999 when Terri Suarez applied for a license to operate an online pharmacy called prescriptiononline.com.

No one at the Nevada State Board of Pharmacy had ever heard of Suarez. She was not a pharmacist. She was not even from Nevada. She was based in Louisiana. But all Suarez had to do to get a license was show that she had a corporation.

"At that time, our whole application was essentially a page and a half," said Ling, the board's counsel. "It was essentially nothing. I don't even think she had to prove she had a business license."

Her application was approved.

Nevada regulators did not know that Suarez operated a closed-door pharmacy in Jefferson, La., called Pharmaceuticals Southwest Inc. On paper, the tiny company was set up to sell discounted drugs to nursing homes. But when an inspector showed up in November 1999, there were no drugs to be found.

"It was definitely a front," Carlos M. Finalet III of the Louisiana Board of Pharmacy said later. "It had no stock. The pharmacist sat there reading a book."

Suarez denied buying any drugs, even when she was confronted with invoices bearing her signature, according to a complaint that the Louisiana board filed against Suarez's company. The board determined that Suarez had indeed purchased drugs -- $1.2 million worth in two months from Bindley Western Industries Inc. But inspectors could not find them.

Based on Suarez's "complete disregard for pharmacy laws," the board revoked the company's license and fined it $100,000. But the board has been unable to collect, and Finalet said Suarez's whereabouts are unknown .

Nevada regulators did not know about Suarez's troubles when her name resurfaced in March 2001. That month, they received notice that she had sold her interest in prescriptiononline.com to Melissa Cosenza, 23.

The regulators blanched. Cosenza's father is Michael R. Cosenza, who has a long history of working at the margins of drug distribution in Nevada and elsewhere.

"We knew immediately that he was using her as a front," Ling said. "What we didn't know was what he was up to."

At a hearing, Melissa Cosenza confirmed that her father was going to be a consultant to prescriptiononline.com. "She had supposedly bought the company for $50,000, payable at $5,000 a year," Ling recalled. "Who buys a pharmacy for $50,000? It sounded as hokey as could be. We started

asking her questions. It was pretty obvious she didn't know anything about the business."

In April 2001, Melissa Cosenza submitted an application for a license, stating that she owned all of the company's stock. She gave a home address near San Diego. Under work history, she listed jobs as a restaurant hostess and salon receptionist.

Nevertheless, she qualified for a license. "I suppose it looks pretty embarrassing but really there wasn't much we could do," Ling said. Under the board's existing rules, "I really can't deny someone a license just because they come from a family and I know they are going to do something bad as soon as I give them a license."

Nor was there much the board could do about Michael Cosenza, 60, whose consulting business Med-Pharm Inc. would be running prescriptiononline.com.

Cosenza had pleaded guilty to grand theft in 1992 in Inyo County, Calif., for stealing more than $100,000 from a health care construction project, court records show. He later was incarcerated in 2000 for six months on a charge related to the earlier case. In October of that year, he had that case dismissed and expunged from his record.

"There was no way Michael as a convicted felon could qualify for a license," Ling said. "But under the law at the time, we didn't have the ability to take action against a pharmacy based on who was employed. It's probably still unclear today if we could stop him from operating the company."

It was not the first time Cosenza had worked around his past.

In April 1997, the California Board of Pharmacy said that Cosenza was operating two closed-door pharmacies licensed under the name of his wife, Barbara Jackson Cosenza. According to the board's official accusation, the two pharmacies were supposed to purchase prescription drugs at a discount and sell them to nursing homes.

"In reality, both pharmacies were actually wholesale businesses in which hundreds of thousands of dollars of dangerous drugs were . . . sold to other wholesale companies," the state board alleged. "Some of these drug shipments were delivered to the San Diego office of a courier and picked up by non-licensed agents. . . . Upon occasion, these dangerous drugs stayed with the courier for days without proper storage or supervision by a registered pharmacist."

According to the accusation, Michael Cosenza had held himself out as the owner of the two pharmacies "and conducted business transactions on behalf of both pharmacies." The California regulators said he did not qualify for a license because of his 1992 felony conviction. In December 1998, Cosenza's wife agreed to surrender the two licenses.

In January 2002, Barnes Wholesale Drugs Inc., a California drug distributor, sued Cosenza. The wholesaler charged that it was owed $529,000 for drugs purchased by an Oregon company called Pharmaceuticals Northwest Inc. The firm was run by Cosenza's stepfather, George Kemmler, 74, a retired snack food deliveryman with diabetes and "blindness in one eye." Barnes alleged that Cosenza paid Kemmler $1,500 a month to act as a straw man. Kemmler declined to comment for this article.

Barnes also alleged that the company was diverting drugs meant for nursing homes to another wholesaler in Las Vegas.

In a deposition, Cosenza denied any role in the diversion. He settled the lawsuit in 2002 by agreeing to pay Barnes $514,000. But he fell behind on the payments, and a judgment was entered against him for $658,000.

Cosenza and his daughter declined to be interviewed for this article. In a court filing in 2003, his lawyer said that prescriptiononline.com was a legitimate pharmacy that complied with all of Nevada's laws and regulations.

Booming Business

With Michael Cosenza behind it, prescriptiononline.com's business surged. Between July and December 2001, the online pharmacy filled 18,499 prescriptions, compared with just 17 in the prior six months. Nearly all were for controlled substances.

"Normally, with any retail pharmacy, you would expect 15 to 20 percent of the sales to be painkillers," Ling said. "Prescriptiononline turned that upside-down. They reversed the model."

Located in a small business park in northwest Las Vegas, prescriptiononline.com did not employ its own physicians. Unlike some other sites, it relied on doctors to steer business its way. All of those physicians were in other states and were associated with middlemen who arranged brief telephone conversations with patients in return for a fee. Two of the doctors -- Jon S. Opsahl and William Dale from California -- quickly became the two most prolific prescription writers in Nevada, regulators said.

In March 2002, Ling told prescriptiononline.com's attorney that he was concerned about the volume of controlled substances. Sherwood N. Cook wrote back that prescriptiononline.com believed that its product mix was consistent with that of other Internet pharmacies, and that "a majority of the drugs filled by Internet and mail-order pharmacies are controlled substances."

One of prescriptiononline.com's customers was Nancy Harler, a former nurse, of Columbia, S.C. She had been getting her painkillers from thepillbox.com. But after that site's legal problems arose, prescriptiononline.com began filling her orders for hydrocodone.

Harler said she had started ordering hydrocodone online for migraines and arthritis in February 2000. In all, she estimated that she spent $10,000 and used more than 1,500 pills. "It just got to the point where I was no longer in control and knew I needed help," she said.

Harler is now undergoing methadone treatment for her addiction, which she said was fed by the online pharmacies. "If you ask them anything about the money, they say we'll be glad to pull the plug. They know they have addicts on the line," she said.

Most of prescriptiononline.com's customers sought painkillers. The Post's analysis showed nearly 90 percent of the orders were for controlled substances, including hydrocodone and the generic equivalents of Valium and Xanax.

For years, hydrocodone has been one of the most used and abused drugs, according to the DEA. Sales have soared, and so have thefts of the drug and hydrocodone-related emergency room admissions.

The street value of hydrocodone is also climbing, said Tony King, the agent in charge of the DEA's Louisville office. A single generic tablet that costs an online pharmacy 15 cents may be sold to Internet customers for $1.50. On the street, that same tablet may go for "$3 to $5," King said. Overall sales of

hydrocodone in Kentucky have doubled in the past four years, to 120 million tablets.

The surge began a few years back, when doctors alarmed by OxyContin abuse began switching patients to hydrocodone, King said. "But hydrocodone is equally dangerous," he said. "It's kind of like: Do you use a .38- or .40-caliber gun to shoot yourself?"

A breakdown of prescriptiononline.com's sales by Zip code revealed that four of every 10 pills flowed into Alabama, Tennessee, Louisiana and Kentucky. Those four states routinely rank among the top five nationally in the per-capita use of hydrocodone and Xanax, according to law enforcement data.

The pills poured into small towns. In Hope, Ky., with a population of 152, customers bought 7,910 pills -- an average of 52 pills for each resident. In Gunlock, Ky., population 430, customers bought 2,910 pills, about seven per person. By contrast, in Louisville, Kentucky's biggest city with a population of 206,239, customers bought 5,810 pills, about 0.03 per person.

In some cases, these orders went to multiple customers listed at the same address. For example, over five months 2,030 pills were shipped to five customers at one home in Baileyton, Ala. More than 80 percent were hydrocodone.

In an interview, Opsahl, the California physician who wrote the prescriptions, said he was aware that customers occasionally listed the same address, but not to the extent detailed in The Post analysis. "I didn't have that data at the time," he said, calling the information "very disturbing. You've presented some information that certainly gives me some pause how this whole system can be blatantly abused and easily abused."

Still, Opsahl maintained that most Internet patients have legitimate needs.

That view is not shared by Mike Vories, a physician who runs a pain management clinic in Hazzard, Ky.

"How in the world does an Internet Web site have any control over whether that controlled substance is going to a patient with a legitimate complaint?" he wondered. "Really, come on. Let's call this for what it is. A few maybe are legitimate and have pain. For the majority, it is a source of income."

Long Investigation

Alarmed by prescriptiononline.com's sales of controlled substances, Nevada regulators alerted the Las Vegas office of the DEA in the summer of 2001. Ling hoped for quick action. But the investigation stretched over months.

In the fall of 2001, DEA agents made undercover purchases from the Web site. In March 2002, DEA agents searched prescriptiononline.com's small office and seized business records. But the agents allowed the company to remain in business.

It would be 10 months before the DEA took away prescriptiononline.com's license to sell narcotics, declaring it "an imminent danger to the public health and safety" and seizing 21 boxes of drugs worth $143,000. By then, the company had moved about 1.8 million more doses of dangerous drugs.

When the DEA acted, the pharmacy board formally accused prescriptiononline.com of more than two dozen violations, including dispensing dangerous drugs where there was no valid physician-patient relationship.

On Jan. 22, Michael Cosenza and prescriptiononline.com agreed to relinquish the company's license and pay $200,000 in fines. The deal prohibited Cosenza or any member of his family from applying for a pharmacy license in Nevada for two years.

Melissa Cosenza did not attend the hearing.

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Internet Cases

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THEPILLBOX.COM

Texas pharmacist William A. Stallknecht began selling Viagra online five years ago to customers in Australia, Canada, Mexico and the United States. At first, he was "fabulously successful," his former business partner said. But the market became crowded with other Internet pharmacies. Stallknecht, 57, shifted to selling the painkiller hydrocodone and other controlled substances through his San Antonio Web site.

Customers contacting thepillbox.com would be steered to a physician referral service he owned. After a brief telephone conversation, a doctor would write a prescription and fax it to Stallknecht, who received half of the $100 "consulting" fee, as well as any profits from selling the drugs.

Before it was forced to stop selling prescription drugs in November 2001, thepillbox.com generated more than $7.7 million from controlled substances, netting as much as $300,000 a month, according to court records. The online pharmacy sold more than 8.4 million doses of hydrocodone and Diazepam. "It was just an easy way to get drugs, either to abuse it or to sell it," said Jerry Ellis of the Drug Enforcement Administration's Houston office, which conducted an 18-month investigation of the online pharmacy.

In March 2002, the government indicted Stallknecht, three doctors and Brian Hilldebrand, operator of the referral service. All have pleaded guilty to illegally dispensing hydrocodone and are awaiting sentencing. Stallknecht forfeited $1 million and his pharmacy license.

MYPRIVATEDOC.COM

Jeffrey N. Finnell decided to sell prescription drugs online in the summer of 2000. Operating out of his auto repair business in Mesa, Ariz., he and his partner, Patrick Dixon, started myprivatedoc.com and two other Web sites. They quickly attracted thousands of customers seeking an array of painkillers and other controlled substances. Doctors in eight states, including Alaska, Florida and Idaho, wrote the prescriptions. Drugstores in California and Arizona filled the orders.

In June 2002, federal prosecutors in Arizona moved to seize several million dollars in assets from the Web sites, owners, doctors and pharmacies. The prosecutors estimated that in a 14-month period, the operation handled more than 35,000 prescriptions and dispensed 2 million doses of controlled substances. According to court records, the Web sites grossed an estimated $4 million, with Finnell receiving $726,000 and Dixon, $719,000.

In its civil complaint, the government said customers paid inflated prices and tolerated "the delay because either they had no doctor who would prescribe the drugs . . . or they sought to avoid scrutiny."

Finnell declined to be interviewed. Dixon said they started the business to "fill a niche" and voluntarily closed when the DEA informed them they were violating the law.

MEDICATIONSEXPRESS.COM

Food and Drug Administration investigators trolling the Internet discovered Gerald Bevins's Web site in 1998. In October of that year, they boarded his motor home after he wheeled it into the parking lot of a McDonald's near San Diego. Inside, they seized the painkillers Percodan and Darvon, which Bevins had purchased in Mexico.

Along with his wife and daughter, Bevins was operating a mail-order business that sold Mexican drugs. No prescriptions were required. Bevins accepted only money orders. He would either drive to Mexico or use a runner to pick up the drugs, which he then repackaged and shipped via Federal Express. To avoid detection by customs inspectors, he instructed his runners to change license plates before crossing the border, according to his plea agreement.

Bevins imported Ritalin, Valium, Percodan and Clonazepam, a "date rape" drug. He made between $800,000 and $1.5 million in profit.

In September 2001, Bevins was sentenced to two years in federal prison. His wife died before sentencing. His daughter pleaded guilty to helping to bring in "misbranded drugs" and received probation.

SUCCESS123.COM

Carl D. Roberts insists all he wanted to do was help people. After his wife was hit by a drunk driver, he set up a Web site in his home in Powell, Tenn., to find innovative drugs for treating brain injuries. But his site turned into something entirely different, federal prosecutors maintain.

According to court records, success123.com (also known as the Mail Order Pharmacy) was a portal for customers seeking OxyContin. For as much as $500, subscribers could purchase "gold" and "deluxe" memberships that provided exclusive access to suppliers in Mexico, the Netherlands and elsewhere.

Roberts pleaded guilty to dispensing controlled substances in September 2002 and was sentenced to 57 months.

Aiding Roberts with his site were others he met online.

Frank N. Assaf Jr. had connections to a Mexican pharmacist who supplied him with thousands of OxyContin tablets. Gold members e-mailed orders to Assaf.

Between 2000 and 2002, he received about $2.1 million. Assaf kept cash in two safes at his Tucson home and in bank accounts under aliases, including one in Riga, Latvia. In a November 2002 raid, agents found 50,200 pills, ampules and tablets at the house. According to Assaf's computer inventory, two customers had spent more than $50,000 and 22 had spent more than $20,000. In August, Assaf pleaded guilty to illegally distributing OxyContin and was sentenced to 44 months.

NATIONPHARMACY.COM

Investigators were stunned when they visited the tiny storefront offices of the Internet-based pharmacy in Norman, Okla., in December 2000. Barely open two months, it was filling hundreds of prescriptions daily for its nationpharmacy.com Web site, the Internet arm of a brick-and-mortar drugstore called Main Street Pharmacy.

"There were cases of hydrocodone from ceiling to floor in a room that was maybe 8 by 8," said Cindy Hamilton of the Oklahoma State Board of Pharmacy. "You couldn't maneuver."

In March 2001, the state agency revoked the pharmacy's license. The owner, pharmacist Clayton Fuchs, 32, was indicted in Texas on related charges, along with three doctors, two pharmacists and a business partner. The doctors have pleaded guilty. Fuchs is awaiting trial and has appealed the pharmacy board's ruling. According to pharmacy board records, Main Street sold about 1.5 million doses of hydrocodone in four months. Profits from Fuchs's Internet operations were used to purchase a $675,000 house, $505,851 in other real estate, a $92,650 Mercedes, a 2001 BMW and a 1.735-carat diamond ring, the federal indictment states.

Through his lawyer, Fuchs declined to be interviewed.

"That business was like a Home Shopping Network for hydrocodone," said John Duncan, chief agent of the Oklahoma Bureau of Narcotics and Dangerous Drugs. "All they were doing there was pushing dope."

-- By Gilbert M. Gaul

and Mary Pat Flaherty

How Drugs Get to You

Prescription drugs normally flow in a straight line from pharmaceutical manufacturers to patients. But billions of dollars worth of prescription drugs are now bought and sold in a vast, unregulated shadow market that includes both legal operations and rogue medical merchants. More and more Americans are exposed to deadly risks.

LEGAL WAY

Manufacturers
Manufacturers sell their drugs to large wholesalers and authorized distributors.

Wholesalers
There are three large wholesalers, AmerisourceBergen, Cardinal Health and McKesson, and scores of smaller distributors.

Retail pharmacies
Wholesalers sell drugs to retail pharmacies.

Patients
Patients buy drugs.

THE SHADOW MARKET

Drug Diversion

Pharmacies that serve nursing homes, clinics and hospices obtain deep discounts of as much as 80 percent from drug makers, pledging not to resell the drugs. But some illegally divert the drugs to small wholesalers.

Optia Medical, a small wholesaler with Las Vegas and Salt Lake City

A victim
Maxine Blount, 61, of St. Charles, Mo., received a diluted cancer drug that passed through several wholesalers to her drugstore. She later died of her cancer.

A case
Requirements Inc., operating out of a garage in Georgia, bought discounted drugs from Pharmacia-Upjohn, ostensibly for Native American clinics. Instead, it sold the drugs to Las Vegas wholesaler Cyprus Resources, which resold them. The scheme cost the drugmaker $2 million in 12 months.

Example drug
Accupril, a blood pressure medicine, is among drugs frequently diverted by small wholesalers, according to some regulators.

Internet

Millions of Americans are bypassing their doctors and pharmacies to buy drugs online. With no medical records or exams, they are able to obtain narcotics and other dangerous drugs.

Prescriptionsonline.com of Las Vegas sold nearly 5 million doses of painkillers and controlled substances in 18 months.

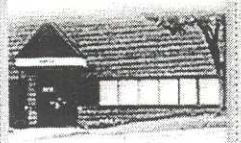
A victim
Douglas L. Townsend, 30, of Aiken, S.C., took a drug he bought from an Arizona Web site and died when he crashed his car after taking the tranquilizer Xanax.

A case
Success123.com, also known as the Mail Order Pharmacy, was a Web site for patients seeking OxyContin and other addictive drugs. Customers paid a fee to access suppliers in Mexico and the Netherlands. Federal prosecutors shut the Tennessee operation in 2002.

Example drug
Hydrocodone (generic Vicodin), an addictive painkiller, is one of the most commonly sold drugs online.

Counterfeit

Counterfeiters sell diluted, tainted and fake medications that they buy or manufacture inside and outside the United States. They also buy medication on the streets from Medicaid patients and repackage it as new.



G&K Pharma of Odenton, Md., allegedly shipped a diluted drug needed by HIV patients to a Miami drugstore in October 2002.

A seller
Michael Carlow and 17 others were indicted in Florida in July on charges of selling counterfeit and tainted medications.

A case
Most of the $8.5 million worth of the cancer-treating drug **Epogen** AmerisourceBergen bought between April 2001 and May 2002 was found to be one-twentieth of its labeled strength, according to court records. Some of the 2,082 boxes already had been used by patients.

Example drug
Nearly 200,000 tablets of **Lipitor** were recalled this summer after fakes and foreign versions of the cholesterol-lowering drug were found at a wholesaler in Kansas City, Mo.

Cross-border traffic

Prescription drugs now pour unimpeded across America's borders from Internet pharmacies and cross-border traffic. Mexico and Canada are on the front line.

Joyce Ernst, 65, of Las Vegas buys Xenical in a pharmacy in Tijuana, Mexico, at a steep discount from the U.S. price.

A victim
38-year-old **Todd Rode** of Chicago overdosed on drugs he bought from an online pharmacy in South Africa.

A case
Gerald Bevins drove his motor home to Mexico to buy Ritalin and other drugs. Bevins advertised the drugs on his Web site, medications-express.com. Federal investigators caught Bevins repackaging drugs in the back of his motor home. He was sentenced to two years in prison.

Example drug
Drugs such as this generic **Prozac** are popular with Americans at Mexican pharmacies.

SOURCE Washington Post reporting by Mary Pat Flaherty and Gilbert M. Gaul

GRAPHIC BY LAURA STANTON—THE WASHINGTON POST

PHOTO CREDITS: Optia photo courtesy of NEVADA STATE BOARD OF PHARMACY; prescription online.com photo BY GILBERT GAUL—THE WASHINGTON POST; G&K photo BY JONATHAN NEWTON—THE WASHINGTON POST; Mexico photo BY FIELD CREAVES FOR THE WASHINGTON POST.

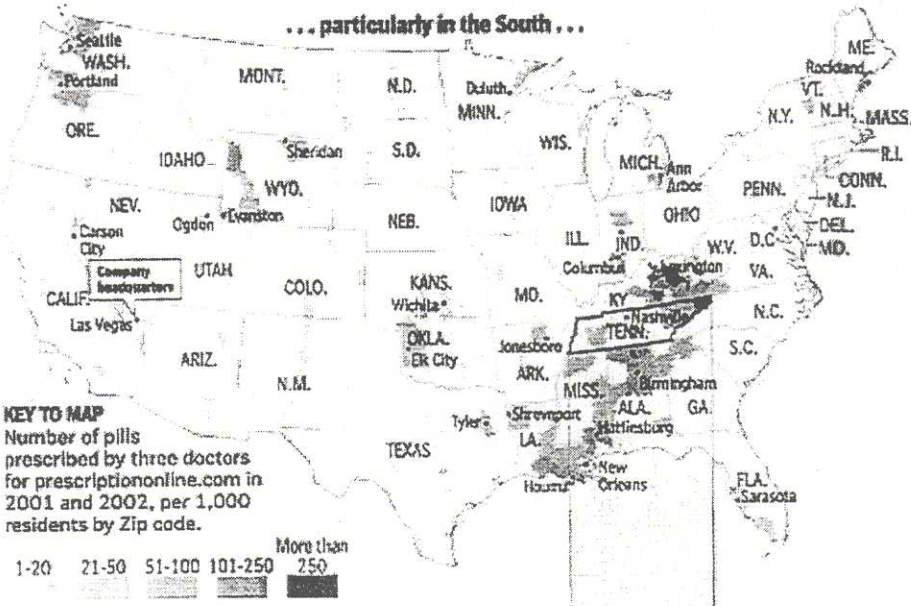
The New Narcotics Pipeline

Six months after it was launched in 2001, prescriptiononline.com, an Internet pharmacy based in Las Vegas, was selling an enormous amount of controlled substances, including 10 percent of all the painkiller hydrocodone sold in Nevada. A disproportionate share went to s in four southern states: Kentucky, Tennessee, Alabama and . Regulators shut down the pharmacy in January 2003.

A sales explosion . . .

Doses of controlled substances sold by prescriptiononline.com increased by nearly 100-fold between June and July 2001.

. . . particularly in the South . . .



KEY TO MAP
Number of pills prescribed by three doctors for prescriptiononline.com in 2001 and 2002, per 1,000 residents by Zip code.

1-20 | 21-50 | 51-100 | 101-250 | More than 250

. . . of cont

Two control accounted f drugs sold prescription

Breakdown of

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About the

Hydrocod
Vicodin, painkiller

Alprazolar
Xanax, is drug for

The Tennessee Example

A Washington Post analysis of prescription patterns at prescriptiononline.com by Zip code shows that far more of the hydrocodone went to small towns than to big cities in Tennessee.

Number of pills purchased from prescriptiononline.com, 2001-2002

In larger Tennessee cities, the number of pills per person was relatively small.

	Population	Pills	Pills per thousand residents
Memphis	766,810	10,370	14
Chattanooga	189,649	3,965	21
Nashville	412,511	10,800	26
Knoxville	346,766	11,710	34

In some smaller towns, the number of pills sold by prescriptiononline.com exceeded the population. Some of the prescriptions were sent to post office boxes and to addresses where as many as five people were listed as buyers.

SMALL TOWNS	Population	Pills	Pills per thousand residents
Piney Flats	6,499	6,570	1,000
Church Hill	18,366	18,610	1,013
New Tazewell	7,823	9,960	1,273
Bristol	38,592	61,752	1,584
Mountain Home	404	1,170	2,896

NOTE: Populations are based on Zip code.
SOURCE: Nevada State Board of Pharmacy. Washington Post analysis by database editor Sarah Cohen

BY SARAH COHEN, GILBERT GAUL AND LAURA STANT

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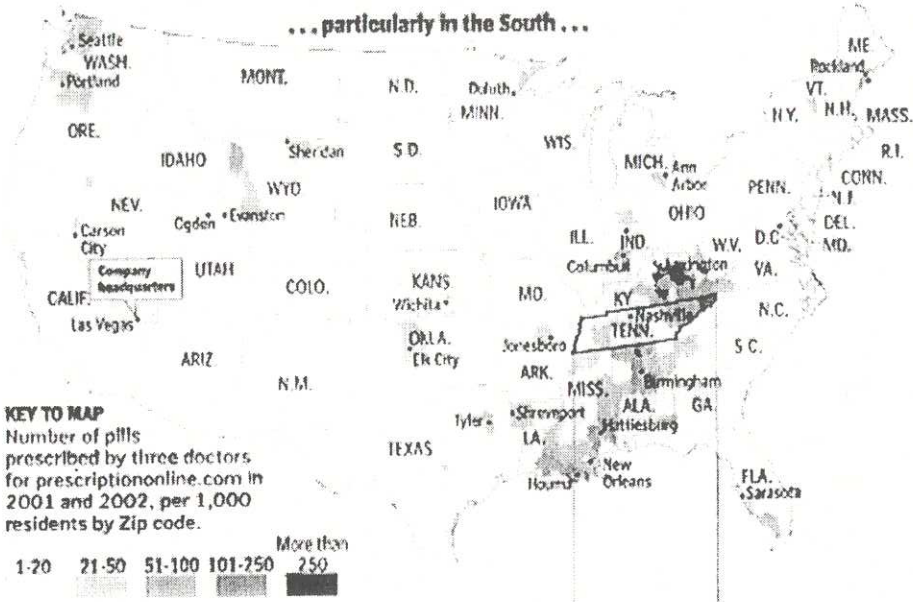

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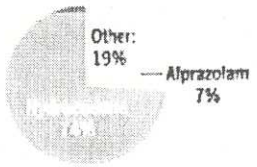
Two controlled substances accounted for 80 percent of all drugs sold over the Internet by prescriptiononline.com:

Breakdown of doses by type of drug

18-month dose total: **4,868,214**



About the Drugs

Hydrocodone, or generic Vicodin, is a schedule III painkiller.

Alprazolam, or generic Xanax, is a schedule IV drug for treating anxiety.

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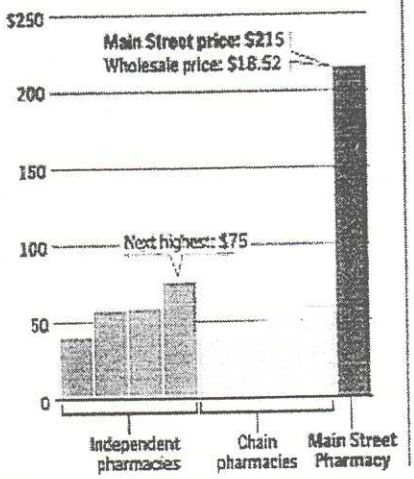
BY SARAH COHEN, GILBERT GAUL AND LAURA STANTON—THE WASHINGTON POST

Main Street Mark-Ups

Main Street Pharmacy, an Internet pharmacy based in Oklahoma, was shut down in 2001 and the owners were indicted on federal charges in 2002. A look at their operations:

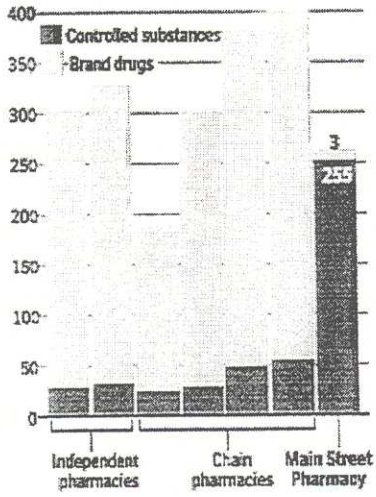
Main Street charged extreme mark-ups for controlled substances it sold in 2001, pricing the drugs much higher than other pharmacies. The painkiller hydrocodone was Main Street's best seller.

Price various pharmacies charged for hydrocodone in 2001



On average, Main Street sold approximately five times the number of controlled substances as other Oklahoma pharmacies. Unlike other pharmacies, they sold almost no other brand drugs.

Prescriptions dispensed in an average day



SOURCE: Oklahoma State Board of Pharmacy

THE WASHINGTON POST

washingtonpost.com

Doctors Medicate Strangers on Web

Some Physicians Face Own Troubles

By Gilbert M. Gaul and Mary Pat Flaherty
Washington Post Staff Writers
Tuesday, October 21, 2003; Page A01

Third of five articles

SAN ANTONIO -- At his worst, Ernesto A. Cantu was injecting himself 10 times a day with Demerol, swallowing tablet after tablet of hydrocodone, taking Ambien to sleep and using Valium for anxiety.

"I became addicted," the stocky 60-year-old doctor said. "It's an illness."

Even as Cantu wrestled with his own addiction, he was writing thousands of prescriptions for painkillers for customers of the Internet pharmacy thepillbox.com. Those orders were based on brief telephone conversations with patients Cantu never examined or even met. All together, he approved more than 1 million doses of hydrocodone and other dangerous drugs, court records show.

At least five of Cantu's customers were addicts or later became addicted, according to state and federal records. An Alabama patient suffering from chronic alcohol abuse and depression overdosed on hydrocodone and was hospitalized for nine months. A San Francisco patient addicted to narcotics developed liver damage after receiving multiple orders of the painkiller Darvocet. A New Jersey mother previously treated for substance abuse received more than 800 doses of hydrocodone from Cantu and other thepillbox.com doctors.

Cantu earned as much as $1,500 a day for writing Internet prescriptions. In nearly eight months, he said, he made $147,000. Other online doctors have made as much as $500,000 a year.

"This is not Albert Schweitzer on the other end of the computer box," said Lee S. Anderson, a physician and president of the Texas State Board of Medical Examiners. "The people who are doing this know exactly what they are doing -- and they are doing it for the money."

Across America, doctors beset by troubled histories work for rogue Internet pharmacies, grinding out tens of thousands of prescriptions each year for narcotics and other controlled substances. What passes for medicine in these online transactions is mostly a fiction. There are no medical records, examinations, lab tests or follow-ups.

The doctors are recruited by middlemen who link them to Internet customers seeking access to the coveted drugs. The result is a virtual pain-management industry that feeds millions of doses of highly addictive drugs into the shadow market for pharmaceuticals, bypassing the normal checks and balances in the physician-patient relationship.

"It's an easy way to make big bucks," said Jerry Ellis of the Drug Enforcement Administration's Houston office. "It's not like any of the doctors are truly practicing medicine or caring for the patients."

Internet pharmacies have attracted doctors with substance abuse problems, legal setbacks and financial woes.

Among them:

David L. Bryson: After losing his job as a staff physician for a state facility in Texas, the 65-year-old joined thepillbox.com in 1999 after reading a newspaper article about its owner. Bryson had undergone alcohol dependency treatment in 1995 and filed for bankruptcy protection in 1999, according to Texas medical board records. In fewer than three years for thepillbox.com, he wrote 20,000 prescriptions for more than 4.7 million doses and collected nearly $1 million in fees, records show. About three-quarters of the prescriptions were for hydrocodone and Xanax. In 2002, the Texas board revoked his license for prescribing dangerous drugs to people he had not examined. A consultant to the board called Bryson's actions "a travesty." Bryson pleaded guilty last month in a related federal case and is awaiting sentencing. He declined to comment through his attorney.

Allen L. Browne: In 1999, the 46-year-old obstetrician pleaded guilty to sexual exploitation of a minor and was sentenced to 10 months in prison. Browne was caught secretly videotaping his girlfriend's 13-year-old daughter showering and using the bathroom in his home in Mesa, Ariz. He kept his license but closed his practice in March 2001. Soon after, he began writing prescriptions for hydrocodone, codeine and Alprazolam for a Web site based in a Mesa auto parts store. In seven months, Browne wrote 2,568 prescriptions, earning $36,520. He surrendered his medical license earlier this year. He admitted to the board that customers might have misled him to get pills. Browne could not be reached to comment for this story.

Marvin Gibbs: The 55-year-old gynecologist had recently lost privileges at an Arizona hospital, where he saw 90 percent of his patients, when he was approached in 2000 to write prescriptions for an online pharmacy. In 10 months, he wrote more than 9,000 prescriptions for more than 700,000 doses of controlled substances, according to records of the Arizona Board of Medical Examiners. "What in God's name were you thinking," a board member asked during a 2002 hearing, "prescribing to folks you have no idea who they are, where they're coming from, what they're doing with the medications?" In February, the board placed Gibbs on 10 years' probation. He did not respond to an interview request.

Ricky Joe Nelson: Unemployed and reeling financially after the collapse of a business venture, the 47-year-old physician signed on in 2001 to write prescriptions for an Internet pharmacy in Oklahoma. In a few months, he wrote more than 5,000 prescriptions for controlled substances. In 2002, a federal jury convicted him of conspiring to distribute controlled drugs and launder $175,000 through an offshore bank account. He was sentenced to 51 months. He declined to be interviewed.

Many other cases bear out that there are few checks on doctors who hand out drugs over the Internet:

A Colorado doctor had a history of alcohol abuse. An Arkansas doctor was being treated for bipolar disorder and drug dependency. A Florida doctor had twice been cited for providing inadequate care to elderly patients, one of whom died. A Texas doctor was under investigation by the FBI for suspected Medicare fraud and later committed suicide. A California doctor was disciplined for operating under a fictitious name. A North Carolina doctor had held 22 jobs in five years.

Prescriptions Without Exams

Doctors who write prescriptions for Internet pharmacies maintain that the practice is safe and serves people who might otherwise not have access to painkillers and other medicines.

Cantu, for example, told The Washington Post in an interview that his earlier experience working in a hospital emergency room helped him identify online patients who might abuse drugs. "Yes, it would

certainly be better if I saw them, but this is a new form of communication," he said.

Others stressed that many of their patients were between jobs, uninsured or had no regular doctor. The Internet sites allow them to refill prescriptions quickly without having to find another physician.

State and federal regulators say all of these arguments lead to a larger question: What should physicians reasonably be expected to do before they write a prescription for a dangerous drug?

In the past, the answer was relatively simple. Patients went to the doctor's office and were examined. The doctor saw the patient face-to-face "and could form an opinion whether there was drug-seeking behavior," said Anderson of the Texas State Board of Medical Examiners.

The rise of the Internet complicated matters. The doctor did not see or know the patient and the patient had little, if any, information about the doctor. Initially, all the patient had to do was fill out a short online form. Later, as regulators started to raise questions, many Web sites added a brief telephone consultation. But those were often little more than a few stock questions. And there usually were no medical records, tests or histories.

In 1999, the Texas medical board adopted rules for the Internet that require a face-to-face examination. "We were concerned that the Internet would foment drug-seeking behavior," Anderson said. "We also felt that the traditional physician-patient relationship was being sidetracked, especially for controlled substances. We just felt it was dishonorable."

Since then, other state medical boards have adopted similar rules. But not every state. There is a lingering debate over whether Congress should step in with a federal requirement.

"If each state would adopt and implement guidelines . . . there probably wouldn't be a need for federal legislation," said James N. Thompson, president of the Federation of State Medical Boards. "There is wide variation. Some states are very strict and some states have no enforcement whatsoever."

The borderless nature of the Internet works against state regulation. In one case, a customer in New Jersey visited a site in Arizona that used a doctor in Alaska, while a pharmacy in California filled the order. "Until this happened, medicine was not really an interstate commerce problem," Anderson said.

A uniform rule would allow regulators to track dangerous doctors across state lines.

"Right now if a California doctor did something to a kid in Texas, Texas has no authority over that," said Jon E. Porter, a lawyer who formerly directed compliance at the Texas medical board. "We have no idea how many people are being hurt. I think there are hundreds, if not thousands, of cases we don't know about. I think it is a huge crisis that the federal government has ignored."

In the late 1990s, Congress considered requiring Internet pharmacies to disclose basic information about themselves and the doctors they used. But the debate was bogged down in arguments over jurisdiction and fears of harming e-commerce. Currently, customers logging on to most online pharmacies and doctor referral Web sites receive little information.

Some Internet doctors have been hired by e-mail; others after they walked into pharmacies. Cantu was offered a job when he visited thepillbox.com to buy supplies for his diet center. Sandra G. LaFon, a board-certified internist from Texas, was hired in 2000 by thepillbox.com while she was home recuperating from a broken back.

LaFon said she originally thought the site was "a real business." But after a few months she became alarmed when customers began to call her asking for controlled substances.

"I had lots of people tell me they fell off the roof," she said. "I heard all kinds of lies. Alarms went off. I thought, this is getting out of control. When I found out a patient absolutely fabricated a whole story, I quit."

William A. Stallknecht, the owner of thepillbox.com, pleaded guilty to illegally dispensing controlled substances. He declined to comment through his attorney.

For her role in thepillbox.com, LaFon, 39, was fined $1,000 by the Texas medical board and ordered to take 10 hours of continuing medical education in risk management. She considers herself lucky. "I could have lost my license over this. I'm not like those other guys. I didn't write 400 scripts a day. The moment I found out things stunk, I got out."

A Doctor's Downfall

Sitting in a glass-enclosed visitors cubicle in a federal prison in San Antonio, Ernesto Cantu's voice falls to a whisper as he wonders whether there is any chance he will get his medical license back. His drab blue prison garb bears a vague resemblance to a surgeon's gown, but otherwise there are few hints of his medical past. Ever so slowly, Cantu's mouth tightens into a sad smile. "I guess that's wishful thinking," he says, answering his own question. "But I can still hope."

At the moment, all Cantu faces is the prospect of more time in prison. In October 2002, he pleaded guilty in two state cases for attempting to buy Demerol with a fictitious prescription and for sexually molesting a 1[illegible]-year-old girl. That same month, he also pleaded guilty to a federal charge of conspiracy to dispense controlled substances for thepillbox.com.

He was sentenced to six years on the state charges. He is now being held in the federal facility while awaiting sentencing for the federal charge. He faces as many as five years in prison and a $250,000 fine.

Cantu has fallen far.

He grew up in Brownsville, Tex., on the Mexican border, the eldest of six children. His parents owned a fencing company and encouraged their children to study. Cantu was a good student and worked as a pharmacist in south Texas for several years before completing medical school in Guadalajara, Mexico.

After finishing an internship in Camden, N.J., and working in emergency rooms in south Texas, Cantu relocated to San Antonio in 1987. He eventually set up a diet center in a strip mall, where he worked in the mornings. In the afternoons, he ran a small general practice on the other side of town.

Cantu described his practices as busy, adding that he was clearing $8,000 to $10,000 a month. Still, he had a significant financial problem. He owed the Internal Revenue Service about $80,000. He eventually filed for bankruptcy protection "to keep the IRS from putting liens on me."

That was not his only legal headache. In May 1992, he was charged with assault and making terroristic threats toward his live-in girlfriend. "We had some domestic disputes," Cantu said. The case was dismissed. A 1995 arrest on suspicion of possession of a controlled substance also was dropped.

Cantu started writing prescriptions for thepillbox.com in late 2000 and continued through the summer of

2001. He said he purchased supplies from the Pillbox Pharmacy but did not know that its owner, Stallknecht, had started an Internet business. "I didn't know him that well," he said. "One day he asked me, 'How would you like to join up as a consultant?' "

Cantu said he made informal inquiries into whether prescribing for Internet customers was legal and was assured that it was. Initially, he said, he wrote about 10 prescriptions a day, gradually increasing to 30 or more. He was paid $45 per prescription.

Thepillbox.com used a middleman to arrange the telephone consultations. Cantu said he received some medical records. But as time went on, "the medical records and the diagnoses started to decrease," he said. "I'm not going to sit here and say I had a medical record for every patient."

In hindsight, Cantu said, "I am thinking it is not a good way to practice medicine because there is no way to evaluate the progress of the patient and also make sure the patient is not abusing the medication."

One patient who took advantage of the system was Connie Cuccaro, 44, a New Jersey mother with a 10-year history of substance abuse. Between Dec. 8, 2000, and Jan. 17, 2001, she received 300 tablets of Vicodin, a brand-name version of hydrocodone, from thepillbox.com. That was at least 100 tablets more than the manufacturer's recommended dose for that time period, according to an investigative report prepared for the New Jersey attorney general.

Cuccaro declined to be interviewed. However, in a February 2001 deposition she testified that Cantu never asked her if she had a drug problem.

Q: He never inquired?

A: No. The conversation was less than 10 minutes. Very simple, very quick. I was very surprised when I hung up. I couldn't believe it was that easy.

Cuccaro admitted taking more of the Vicodin than needed. "I am a prescription-drug addict," she told investigators.

In November 2000, Cuccaro was scheduled for another consultation with Cantu but missed the call when she left on a three-day anniversary trip with her husband, Joe. A few days after returning, Cuccaro contacted the doctor referral service to reschedule. The manager said it was not necessary, records show. Her medical chart showed she had already had the consultation. A few days later, Cuccaro received her next shipment of Vicodin, with the number of pills increased from 90 to 100.

At that point, Joe Cuccaro was begging thepillbox.com to stop the shipments, he told The Post.

"They basically laughed at me," he said.

Cantu said he would never have sent Cuccaro more pills without a consultation. "It's not something I would do."

It is easy for patients with drug problems to fool doctors, he said. "They were the ones trying to get these meds. They were the ones who asked for certain meds, who gave symptoms that led you to prescribing certain meds."

Road to Addiction

Cantu's own road to addiction started with the pills he said he took 20 years ago for back pain. "I initially started with Darvocet in the '80s and around 1995 I started using hydrocodone." In October 2000, Cantu added Demerol to the mix. "I briefly became addicted to it."

At the time, Cantu was living with Anne Malley and her teenage daughter in a gated community known as the Enclave.

Although Cantu's signature appeared on the prescriptions he wrote for thepillbox.com, he allowed Malley "to represent herself as Dr. Anne Cantu and provide the telephone consultations with patients," according to the Texas medical board.

Cantu said Malley "did answer the phone at times and speak with patients. But she would not prescribe any medications."

Malley's name appeared on a summary sheet of physicians prescribing drugs for thepillbox.com, according to a 2001 affidavit prepared by a Food and Drug Administration investigator. The affidavit states that she was paid $42,340 by the Internet pharmacy, and used several of the checks as a down payment for a 2001 Mercedes-Benz E350 costing $54,575.

Cantu frequently wrote prescriptions for Demerol in the names of patients and employees who had not sought the drugs, state investigators said.

"The fictitious prescriptions were for the purpose of obtaining Demerol for Respondent's girl friend, Anne Malley, and/or the Respondent himself," the Texas medical board later stated. "There is probable cause to believe that Respondent abused Demerol and/or that he has knowingly aided his girl friend, Anne Malley, in abusing Demerol."

When federal agents searched Cantu and Malley's home in October 2001, they found 96 empty vials of Demerol and syringes in the trash. "At that time," Cantu said, "I did not feel either of us was abusing. But at that time both of us were addicted."

Malley did not respond to repeated interview requests.

Cantu said he was taking as many as 10 tablets of hydrocodone during the day and injecting himself with as many as 10 ampules of Demerol at night. "I didn't use the Demerol during office hours," he said.

He insisted that his addiction did not interfere with his practice of medicine. "Just because a person takes hydrocodone and is addicted to it doesn't mean he can't function in a normal way," he said.

Anderson, head of the Texas medical board, wondered why the board did not catch Cantu sooner. "What he did is shocking," Anderson said. "It is absolutely shocking behavior, and it's totally out of control."

The board did have Cantu on its radar. In October 2000, it alleged that he prescribed "frequent high doses of narcotics" to a patient, including numerous painkillers. Cantu was ordered to complete at least 50 hours of continuing medical education.

Porter, the board's former head of compliance, described the settlement as "garbage." He said Cantu "was handing out drugs left and sideways." Porter said he was worried that Cantu was going to repeat his mistake "and probably hurt somebody."

License Suspended

Cantu said that on Thanksgiving 2001 he prepared a turkey and watched as Malley's daughter and two neighborhood girlfriends roasted marshmallows in the fireplace. He had taken Demerol, Soma (a muscle relaxant), Valium and Ambien. He said he went to bed and blacked out.

According to court records, Cantu returned to the living room, where the girls were sleeping, and fondled a 13-year-old neighbor. The girl raced from the house.

Cantu said he cannot recall the incident. "As to what happened, I have no idea," he said. "I don't remember anything else."

He was charged with indecent sexual contact with a child.

The next month, on Dec. 7, 2001, Cantu's Texas medical license was suspended. But a week later he appeared at a local pharmacy with a prescription he had written for himself for Demerol. An alert pharmacist contacted the DEA and Cantu was arrested. When police searched his car, they found a .22-caliber rifle that Cantu said he purchased at a gun show. Police said it was stolen from the Nashville Police Department.

"It was broken," Cantu said. "Here in Texas everybody has a rifle."

Cantu hopes that he will be released soon and that he will get his license back.

Anderson said, "That is very unlikely."

washingtonpost.com

Experimentation Turns Deadly for One Teenager

By Mary Pat Flaherty and Gilbert M. Gaul
Washington Post Staff Writers
Tuesday, October 21, 2003; Page A15

SAN DIEGO -- Quiksilver was dead.

Word raced through the Internet chat room within hours after his mother found him in the bedroom where his clock radio played on, summoning him for the day he would never see.

Out in the Internet ether, Quiksilver was a guru, a master at mixing the drugs he bought online, a deft chronicler of his own trips.

At home in La Mesa, Calif., Ryan T. Haight had been a teenager smitten with Quiksilver sports clothes, baseball cards and downloading music. He was an honor student, a tennis player, a clerk at a discount store and just barely 18.

After Ryan died on Feb. 12, 2001, his parents found a bottle of the painkiller Vicodin in his room with a label from an out-of-state pharmacy. They called federal drug agents.

The agents resurrected Ryan's double life from the family computer: The teenager ordering addictive drugs online and paying with a debit card his parents gave him to buy baseball cards on eBay.

"Ryan ran and got the mail every day -- and I'm thinking he's all excited getting his baseball cards," said his mother, Francine Haight. "He was getting drugs mailed right to the house. It was so easy."

Without a physical exam or his parents' consent, Ryan had obtained controlled substances. Some came from overseas. Others arrived from an Internet site in Oklahoma. Ryan's slide into drugs took only a few months before it ended in an overdose on a cocktail of painkillers, including hydrocodone (generic Vicodin), an autopsy revealed. He had become a regular on bluelight.nu -- a foreign bulletin board where users share recipes for heady mixes of prescription drugs. Ryan's mother, a nurse, and his father, Bruce Haight, an eye surgeon, knew the dangers of prescription drugs. But "the idea you can buy these on an Internet site and that someone in the medical profession would send them to you without ever seeing you is beyond imagining, beyond horrible," his father said. "How could doctors sell out like that?"

Since Ryan's death, "I've gone on to some of these sites, and once you do that and they have your address, your [Internet] mailbox is full with offers," his mother said.

Ryan's parents thought they had taken precautions. They had insisted that the family computer stay in the den. They did not know Ryan was sneaking from his bed at 1 a.m., ordering drugs and getting high. The clink of ice falling into a glass from the refrigerator door sometimes woke his mother. She thought he simply shared her restlessness. When he slept until noon, "it was like any teenager," his father said. "We weren't lucky enough to get a warning sign, like a trip to the emergency room."

When his parents separated in late 2000, they shared weekends with him.

On the weekend he died, Ryan worked on a cold, rainy Sunday. His mother made him chicken soup in a crockpot. When she talked with him, around midnight, he was listening to music. He hugged her goodnight.

On Monday, the 12th, he slept in. It was not a school day. His mother went out to do errands.

When she returned home about 3 p.m., she saw Ryan's car in the driveway. She had a bad feeling. She went to his room, heard his radio, opened the door and found him. Her attempt at CPR was useless. He had been dead since 2 a.m.

His parents filed a wrongful-death lawsuit against the Oklahoma Web site Main Street Pharmacy. The site's owner, Clayton Fuchs, denies the family's claims, saying they "failed to exercise ordinary care."

Online, Ryan's death was met with disbelief. "I considered Ryan to be the most experienced and wise person I know when it came to drugs . . . I was so incredibly shocked," wrote ZeroHawk. And from beyond the grave came Ryan's own account of one of his last trips, sent in an e-mail started at 10:28 p.m. on Feb. 10, 2001. He had taken drugs he had received "in the mail that day," grabbed a Sprite and ice and wrote of "the little whirlpools of color moving all over. Not TOO much to handle. They were PERFECT."

washingtonpost.com

Web Physician Says He Did No Harm

Thousands of Patients Received Painkillers Without Being Examined

By Gilbert M. Gaul and Mary Pat Flaherty
Washington Post Staff Writers
Tuesday, October 21, 2003; Page A14

COLTON, Calif. -- Even now, nearly a year after he lost his medical license for prescribing powerful painkillers to thousands of Internet customers, Jon S. Opsahl is convinced he did no wrong.

Sitting in his empty office, the 43-year-old physician said he never saw any of those patients, ordered lab work or conducted exams.

Instead, he accepted their word that they were in pain. "Can you legitimize pain over the phone?" he said. "I think you can just as well as you can sitting in a room."

Opsahl said many of the patients "didn't carry a diagnosis other than chronic pain," which he called "a diagnosis in and of itself." Forcing them to see more doctors and undergo additional tests would have been a costly form of medical blackmail.

"They say I committed an extreme departure from the standard of care and was a danger to society," said Opsahl, who was trained in addiction medicine. "I say I chose to believe my patients and was a blessing to them and their families."

In a typical eight-hour shift, he spoke with 30 patients for as many as 10 minutes and spent an hour on paperwork. Over 13 months, he wrote 24,000 prescriptions, including refills, for two Internet pharmacies. He was paid $60 for each telephone consultation and estimates that he received $360,000.

"I went into it totally unaware just how lucrative it could become," Opsahl said. Later, he wrote in an e-mail that he never realized there were "SO MANY chronic pain patients who were not getting the treatment they needed and deserved."

Opsahl said he thinks that patients have turned to Internet sites because the medical system does not adequately recognize pain. "Doctors are afraid to prescribe pain medications out of fear they will be disciplined," he said.

California regulators disagree. Earlier this year, they revoked his license for prescribing medications without "good faith" examinations.

"There is no way that any medically rational monitoring of these patients' ongoing problems can take place," Stephen E. Hjelt, an administrative law judge, wrote in an earlier order suspending Opsahl's license. "It is a supreme challenge to practice medicine with patients face to face. It is a virtual impossibility to do so . . . when the only contact between physician and patient takes place by phone."

Opsahl's online practice started in April 2001, when he began writing prescriptions for customers of thepillbox.com, a San Antonio Web site. When federal regulators closed that site's pharmacy operations a few months later, he switched to a Las Vegas site, prescriptiononline.com. It was shut in December 2002.

Opsahl said the prescriptions were for low-level doses, "a month's supply for patients with migraine headaches, back pain. They were all fairly young, thirties, forties, fifties, all employed, just trying to get through the day or a better night's sleep."

He said the medical records he received were "quite sketchy and inconsistent." Some of the doctors he took over for were "just taking an order for drugs over the telephone . . . cutting all kinds of corners."

A Washington Post analysis of Opsahl's prescribing patterns for prescriptiononline.com found that 95 percent of the 14,785 prescriptions he wrote were for three drugs -- the painkiller hydrocodone and generic Valium and Xanax. In some cases, the drugs went to multiple patients listed at the same address.

"This is new information," Opsahl said when shown the analysis. "I am surprised it is that extensive." In an e-mail, he wrote, "I was particularly disturbed by the incidence of multiple patients at the same mailing address."

These days, Opsahl is still helping patients get painkillers, though he stresses he no longer practices medicine. Through his Web site, optihealth.net, he collects medical records and arranges phone consultations for patients with another physician, whom he declined to identify. In return, he receives a share of the $100 consultation fee.

"I've taken on the role of an administrator," he said.

washingtonpost.com

Lax System Allows Criminals To Invade the Supply Chain

By Mary Pat Flaherty and Gilbert M. Gaul
Washington Post Staff Writers
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Fourth of five articles

She had made peace with the indignities of chemotherapy: the baldness and the vomiting. And she had learned to brace for the pain that broke in waves during the end stages of her breast cancer. But the bone-deep fatigue that settled over Maxine Blount was different and troubling.

"I couldn't get out of bed. I was really tired, worn out, exhausted," she said.

Even the costly injections she relied on to rejuvenate her did not help.

"The girls at the cancer suite," as Blount called her nurses, figured it out first, remembering a recent warning about counterfeit medicines in circulation. They checked a remaining vial from the set of four Blount, of St. Charles, Mo., had bought in March 2002 at her drugstore.

She had bad medicine.

Already weak herself, Blount was taking a weakened version of Procrit, which fights fatigue and anemia. Testing confirmed her dose was one-twentieth the strength listed on the packaging -- packaging that was so authentic-looking that it fooled health inspectors.

Blount died last October at age 61, knowing that when she needed the most from her Procrit she had received the least.

"You're very angry," she said in an interview a month before her death. "You have faith in your pharmacy and faith in the medicine, faith in the packaging and the people doing the buying that they know what they're doing. Now, whenever I get my medication I wonder where it's coming from. But what can I do?

"I need it. I have to have it. And I'm scared of it, every time."

At a time when more Americans are relying on medication, their chances of receiving a drug that is fake, diluted or mislabeled have never been so great.

Last summer, a drug wholesaler was forced to recall nearly 200,000 counterfeit and mislabeled Lipitor tablets after patients complained that their medication tasted bitter. In May 2002, investigators discovered that nearly 110,000 bottles of cut-strength Epogen had passed undetected into the open market. In the past three years, counterfeit, adulterated or diluted medications have been found in drug wholesaler warehouses in Maryland, Kentucky and California. Some of the drugs were distributed in Hawaii, Texas, Washington, Arkansas, Tennessee, Louisiana, Mississippi and Alabama.

Driven by advanced technology and old-fashioned greed, a new breed of highly sophisticated criminals has insinuated itself into the system that distributes medication from drug manufacturers to patients.

These rogue operators have sold everything from fake cholesterol-lowering Lipitor to diluted blood-boosting Epogen to saline labeled as the growth hormone Nutropin, and a shadow market reaches from small wholesalers to the nation's largest drug distributors.

Purchase orders, sales records and information from numerous state and federal investigations illustrate how easily counterfeit and mislabeled medication makes its way from the shadow market into the legitimate marketplace.

Recall notices from manufacturers and wholesalers in the past two years strip the problem to its bare, numeric essence: Procrit Lot P002384, Serostim Lot MNK612A, Epogen Lot P002970, Nutropin Lots L9504A3 and L9101A4. Linked to those numbers are patients nationwide.

Blount was a victim of Procrit Lot P002384.

Robert Lynn, an HIV patient in San Diego, was taking the anti-wasting drug Serostim to offset debilitating weight loss. He bought from Lot MNK612A at his drugstore, injected it, and it "burned like hell and raised a knot the size of a quarter" on his stomach. Instead of Serostim, a steroid was found in vials from that lot.

A 17-year-old boy with stunted growth was injected with Nutropin and experienced stinging and swelling. Annabella Foo, chief pharmacist at Bay Area IV Therapy in Sunnyvale, Calif., discovered the clinic had been sold part of counterfeit batches, some of which contained saline or human insulin.

The cut-strength Epogen went to terminally ill patients at Dickinson County Memorial Hospital in Iron Mountain, Mich. The rural 100-bed hospital "had one of its worst days" when it had to break the news about the medicine, which increases red blood cells, pharmacy manager Gary Lindeman said.

The counterfeiters behind those cases have yet to be unmasked.

Increase in Counterfeiting

Pharmaceutical counterfeiting has risen with the 21st century. A slice of the problem can be seen in the increasing number of counterfeiting incidents reported to the Food and Drug Administration, from about five per year in the 1990s to 20 per year since 2000. Those numbers are almost certainly low.

While FDA regulations explicitly demand that drugmakers tell the agency about many other problems with medications -- from testing failures to adverse reactions -- manufacturers who know their product is being counterfeited are not required to report it. The FDA favors a voluntary industry reporting program, contending that introducing a new rule and getting it through Congress would take years, said William K. Hubbard, senior associate commissioner for the FDA.

A convergence of factors helps account for the increase in counterfeits, which by the FDA's definition includes medicine that has been watered down, mislabeled or faked.

Improved desktop printing and digital imaging make it easier to download and duplicate a medication's packaging. Internet sites sell everything from pill-punching machines to special inks that furnish the sophisticated touches needed to turn out convincing finished goods. The rise of bioengineered medicines for otherwise fatal illnesses has driven up demand and cost -- a tempting opening for counterfeiters.

Unsophisticated operators still exist -- people such as Hassib Selbak, who imported fake Viagra stuffed

in teddy bears from China and sold it by mail as a sideline to his Mr. Spotless carpet-cleaning business near Cincinnati, court records show. But the largest counterfeiting operations net millions of dollars and involve networks of front companies able to distribute thousands of boxes of medicines at a time.

The labeling change that recast 110,000 bottles of low-strength $22-a-bottle Epogen as high-strength $445-a-bottle Procrit netted an estimated $46 million for counterfeiters before the scheme was discovered in May 2002. Only 8,000 bottles were seized in a Texas warehouse of Bindley Western Industries Inc., now part of Cardinal Health Inc. of Dublin, Ohio.

Nearly 90 percent of the bad medicine never was recovered, which meant it may have gone to as many as 25,000 cancer and HIV patients.

For buyers with low profit margins, the ballooning price tags on many pharmaceuticals provide incentives to scout for a deal.

The great variation in price for a particular drug -- driven by volume discounts and special buying arrangements -- helps counterfeiters operate because discounts do not draw attention, several industry analysts said. "So long as the same pill can have 20 different prices on it -- which it can, depending on who it's being sold to -- you open the door to all kinds of problems," said Donald deKieffer, an international trade lawyer who tracks pharmaceutical counterfeiting.

Outdated Regulations

Counterfeiters have also been aided by a regulatory system that is struggling to catch up. Even as increasing reports of counterfeiting surfaced nationwide earlier this year, the FDA insisted it was not a major threat. As recently as March, Hubbard said in an interview with The Washington Post that "we don't think counterfeiting is a huge problem or that you need to worry you're going to get a counterfeit drug."

Then came congressional inquiries and this summer's $55 million Lipitor recall, which deKieffer said was "about as hot-button as counterfeiting infant formula."

By July, the FDA announced it had formed a task force on counterfeiting. The agency further stated that bogus products "virtually indistinguishable from the authentic versions" posed "a potentially serious health risk." The FDA blamed some of the rise on wholesalers who "ignore warning signs indicative of illegal or unethical behavior."

In an interim report this month, the task force suggested exploring everything from radio-frequency chips on packaging to enhanced state licensing and increased federal regulation. New technology alone will not solve all the tracking problems, said FDA Commissioner Mark B. McClellan. And even promising technology -- such as the radio-frequency chips -- could take at least months and probably "a few years" to put in place.

"What I see in my world scares me," said Robert Penezic, who recently left a job as a Florida state prosecutor pursuing counterfeiting cases.

Penezic declined to talk about specific examples. He did say that a company might be conned into buying fake drugs once or even twice, but that "if I'm conned three times, that opens up whether I'm conned, or complicit and looking to save money for my bottom line."

Albers Medical Distributors, the small wholesaler in Kansas City, Mo., at the center of the Lipitor recall, was warned by state authorities about its repeated purchases from small, unlicensed wholesalers.

In an administrative complaint filed in April, the Missouri Board of Pharmacy said it flagged Albers between 2000 and 2002 about dozens of the unlicensed wholesalers that appeared in the company's purchasing records. Yet Albers continued to buy from many of them. The last warning was five weeks before the recall.

In August, Florida filed a separate complaint against Albers over $4.6 million in drug purchases in late 2002 that were accompanied by suspicious paperwork. The medications, including the anti-psychotic drug Zyprexa, sometimes arrived without proper labels or in battered boxes missing safety seals, "which should have put Albers on notice to investigate further into the source of the drugs," the complaint reads.

The source of the counterfeit and mislabeled Lipitor remains under investigation. Several federal and state investigators, and some industry security officials briefed on the case, said some of the tablets were overseas versions made by Pfizer Inc., Lipitor's manufacturer, that were hijacked on loading docks and resold as domestic Lipitor. Other tablets appear to be fakes made in Costa Rica and illegally shipped into the United States.

Albers has denied any involvement in counterfeiting and said it relied on a California broker, who put the company in contact with other wholesalers. Albers said it counted on that broker to verify its suppliers' credentials. Laurie Roberts, spokeswoman for Albers, said, "To its knowledge, Albers was conducting business with the utmost integrity." The firm, which has four employees, entered a consent agreement with the Missouri pharmacy board in which it did not admit to the allegations but agreed to a 30-day suspension of its license and a five-year probation.

A Weak Link

In the emerging shadow market for pharmaceuticals, numerous middlemen along a circuitous route may handle a pharmaceutical from the time it leaves the manufacturer to when it arrives at the final point of sale. "Drugmakers know pretty well who they're buying from for their manufacturing," but when it comes to knowing "where every bit of every thing they sell actually goes, it gets foggier," said Myles Culbertson, director of the Physical Science Laboratory at New Mexico State University, who recently headed a task force on product integrity for the FDA.

Culbertson said drugmakers are not like food manufacturers, who "know their sellers and their buyers extremely well and try to keep control on them. The food people are very, very protective of their supply chain because they are very, very protective of their brand."

The criminals who introduce fake medicine exploit this soft spot in the drug industry.

Gregg Jones, a Florida pharmacy investigator, said: "Distribution has been a weak link in the system."

States have their own problems protecting the drug supply chain.

Jones's department issued hundreds of wholesaler licenses through the 1990s, including some to felons with convictions on narcotics charges and other crimes.

Among them was Chantel Banatty, who in July 2000 agreed to surrender to police on charges of being part of a ring that dealt in medication stolen from a Miami hospital, court records show. Earlier that

month, she had received her wholesaling license. Despite her criminal charges, she managed to hold onto the license for two years, handling numerous sales of counterfeit cancer and HIV products, according to a 2002 state Health Department complaint.

Florida began its licensing crackdown in the past year, as police identified more and more companies selling bogus and mishandled drugs.

Counterfeiters also take advantage of criminal channels that have long been used for the illegal diversion of pharmaceuticals. These diverter networks take medicines sold at steep discounts under special contracts to nursing homes or hospices and resell them for great profit. The diverters rely on shady wholesalers that easily obtain licenses in states with lax systems.

The networks now help move counterfeits, said Rick Allen, deputy director of the Georgia Drugs and Narcotics Agency. "Counterfeiting is joined at the hip to diversion -- it's how they get the product to the shelves."

Allen investigated numerous diversion cases in the late 1980s, but that fraud did not draw the attention that recent counterfeiting incidents have.

In the diversion scams, he noted, "They were moving real product -- though you can ask how good care they took of it -- and at the end of a day, the manufacturer still made money, just not as much as they would have if the contract weren't being violated. A dollar was a dollar.

"Counterfeiting? That gets everyone more exercised."

The stakes go even higher when counterfeiters target flagship products, said Aaron Graham, head of security for the drugmaker Purdue Pharma and formerly for Pfizer, and a former investigator for the FDA and Drug Enforcement Administration. "For so many years, companies didn't understand the complexities of the gray-market diversion underworld and appeared not to be taking action," he said. "But when counterfeit drugs started flowing through the gray market, jeopardizing consumer safety and brand integrity, that's when everybody started paying attention."

Big Three Affected

The country's Big Three pharmaceutical distributors -- McKesson Corp. of San Francisco, AmerisourceBergen of Chesterbrook, Pa., and Cardinal Health of Dublin, Ohio -- have bought medication from smaller wholesalers that later was deemed counterfeit.

In 2000, McKesson bought fake Serostim in a chain of sales from small wholesalers that traced back to Dutchess Business Services, a Las Vegas wholesaler, and from there to Crystal Coast Inc., a smaller wholesaler in Florida, the Nevada State Board of Pharmacy alleges. The board is seeking to revoke Dutchess's license. Steve Gibson, the wholesaler's attorney, said, "My client does not believe it is culpable or contravened any regulation with the state of Nevada."

Crystal Coast has since lost its license over a separate incident involving the sale of counterfeit Nutropin. More recently, the company's owner was arrested on suspicion of selling the pricey prostate cancer drug Lupron, which he bought from doctors and illegally distributed from his Coconut Grove home, Florida records show.

The owner, who had been deported from the United States on a narcotics conviction, said he is a

Norwegian citizen, arrest records show. He is being held under the name he gave: Per Loyning. His attorney did not respond to requests for an interview.

Loyning did business with a South Carolina wholesaler, records show. The company was open for just four months in Charleston. The corporation's name was Rekcus -- "sucker" spelled backward, investigators noted in an arrest warrant.

Some of the Serostim was ultimately sold to Robert Lynn, the San Diego HIV patient. Lynn filed a lawsuit against his drugstore and McKesson. In a settlement reached last year, McKesson denied wrongdoing or liability, referring to the Serostim as "allegedly counterfeit" in court documents.

"Until this," Lynn said, "I never thought about where my drugstore bought its medicine. Now, I don't think about anything but that."

AmerisourceBergen was stung when more than half of $8.5 million worth of Epogen it bought between April 2001 and May 2002 was found to be one-twentieth of its labeled strength, according to a lawsuit the company filed against an Arizona wholesaler. The suit triggered a string of suits as each wholesaler upstream of the Amerisource sale denied it knew the Epogen it passed along was not genuine. The legal actions eventually involved wholesalers in Florida, Tennessee, Utah and Texas.

That lone incident involved 2,082 boxes of Epogen, valued at $4,090 each, the Amerisource suit says. Nearly one-third of the drugs made it to patients, the company said.

Cardinal's problems with counterfeits arose when the company bought 1,353 boxes of Procrit for $2.4 million in 2002 from three smaller wholesalers in Arizona, California and Florida, sales records obtained by The Post show. The three wholesalers, in turn, had purchased the Procrit from five other wholesalers in Tennessee, Florida, New York and California, records show.

The sales records obtained by The Post show Cardinal paid between $1,691 and $1,727 for each four-vial box of Procrit it bought from the smaller wholesalers. At the time, the manufacturer's price was slightly less than $1,780.

That lot turned out to be tainted: In March 2002, Maxine Blount bought some of it from her pharmacy at Schnuck Markets. Schnuck's does not keep the high-priced drug in stock and buys it to fill individual orders, said Lori Willis, a spokeswoman. "Our only source for this medication is Cardinal," she said. Cardinal charged Schnuck's $1,783 and Schnuck's charged Blount $1,850 for a four-vial box, Willis confirmed.

In response to a lawsuit brought by Blount, Cardinal denied selling the specific vials Blount received, according to Don Downing, Blount's attorney.

Cardinal declined to talk about the Blount case or the sales records.

Measures to Fight Fakes

As a result of these and other incidents, the Big Three wholesalers say they have increased their anti-counterfeiting efforts. They say they limit purchases from smaller wholesalers to no more than 3 percent. They also say they have become more aggressive at policing suppliers and now buy certain expensive drugs -- cancer medicines, injectables and biotech drugs -- only from the manufacturers.

Some customers of the Big Three wholesalers said they were shocked that the large companies bought drugs from firms with only three or four employees.

"It's startling they would go dipping into that pool," said Nancy A. Andrew, who heads the pharmacy purchasing team at Legacy Good Samaritan Hospital in Portland, Ore.

The hospitals, drugstores and doctors' offices that dispense medications often know little about the winding paths of the drugs they buy. They know the seller they dealt with, but they do not automatically see all the paperwork that is supposed to reveal every prior sale. That pedigree paper, as it is known, passes only from wholesaler to wholesaler. It is closely held by wholesalers who do not want to risk being cut out as middlemen by divulging too much pricing information.

Like the drugs, the pedigree papers are vulnerable to counterfeiting.

For example, invoices for $3.2 million worth of various drugs sold between late 2001 and early 2002 to Stone Medical Group, a wholesaler in Boca Raton, Fla., state the original seller was a Cardinal distribution center in Phoenix. But that distribution center was out of business at the time, having burned down a year earlier, Florida inspectors found.

"We were taken," said Adam Runsdorf, president of Stone, which let its wholesaler license lapse rather than remain in business, and now sells medical equipment. "Some guys creep in with bad product, and they ruin your reputation. It's at the point now where you have to be suspicious; you can't assume anymore that it is good."

Over the past two years, several drug manufacturers have made changes to try to thwart criminals. Serono Laboratories Inc. added bar coding on Serostim and eliminated wholesalers' handling of the drug by selling directly to pharmacies. Pfizer adopted a single pricing system to wholesalers for Viagra, a change that makes any discounters suspect. Johnson & Johnson added security markers to its Procrit and plans to do the same with each of its products by 2004.

Still, a pair of Levi's has more anti-counterfeiting features than any prescription drug, said deKieffer, whose clients include Levi Strauss & Co. and several drug manufacturers.

The counterfeiters have also gotten better.

In April 2002, Texas inspectors confiscated a large load of diluted Procrit at a warehouse in Grapevine. They suspected it was counterfeit. But when they compared it with other boxes of Procrit in the warehouse, it appeared identical. Three months later, the Texas inspector realized that both batches were fake.

A stray line through the digit "6" on the Procrit boxes and an accent mark over the "i" in the word sodium were the tip-offs on the second load.

A national recall was issued for the second lot: P002384 -- the same number that had gone to Blount.

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Medicaid Is Start of Drug Resale Trail

By Mary Pat Flaherty and Gilbert M. Gaul
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The box of Trizivir "looked like it had been through the war," Phoenix pharmacist Barbara Renthal recalled thinking in April 2002 as she unpacked the shipping carton containing 10 boxes of the expensive HIV medication.

Then she opened a box and found a bottle with a patient's name on it. The label showed it had been dispensed months earlier at a drugstore in Fort Lauderdale, Fla. A phone call revealed Florida's Medicaid program had paid for it.

Renthal was staring at a small part of a growing fraud nationwide: Poor patients receive high-priced medications through Medicaid and sell them to sophisticated crime rings that pass them around like fenced TV sets, until eventually they get to patients.

The scams thrive because some drug wholesalers and pharmacies are looking for any advantage.

Bioengineered drugs that cost $1,000 a dose and more are especially attractive. But common drugs also have surfaced in the illegal rings: the heart medication Procardia, the heartburn drug Propulsid, the antibiotic Augmentin.

In August, nearly $15 million worth of prescription drugs was seized in New Jersey and New York. As police searched a house on the day of the arrests, a Federal Express truck delivered a package that contained $30,000 in cash from a Florida man believed to be one of the outlets for the pharmaceuticals, New Jersey prosecutor John I. Molinelli said. Drugs were found rebottled in amber vials "with the safety caps, just like you'd see in your drugstore," he said.

Scammers have hired "cleaning crews" that expose medicine to lighter fluid, heat guns and even open flames to peel patient labels from dispensing bottles. "What these drugs are used for in real life is an afterthought," said Ken Karp, a police officer with the New York State Attorney General's Medicaid Fraud Control Unit.

The schemes have burned outlets as large as Caremark Inc., the mail-order pharmacy for Florida state employees and other group plans. In April 2002, the company brought in 70 pharmacists to call patients nationwide to tell them the source of their medications was in doubt.

About 975 people returned medications, costing the company $2 million. Caremark had purchased the drugs from a Florida wholesaler who bought from another Florida wholesaler linked to a fraud ring, state investigators found. The ringleader is believed to be in Venezuela. Caremark said it no longer deals with small suppliers.

Two brothers sentenced in Trenton, N.J., in April sold to drugstores in New Jersey, Georgia and Louisiana, court records show. Godwin and Patrick Okoye were in a ring that cost Medicaid $5 million, prosecutors said. They did not respond to interview requests.

Horace Bynum Sr. bought Procardia from the Okoyes for his New Orleans pharmacy a few years ago, Bynum, 86, recalled. "I wanted to give someone else a hand who was young and starting out," he said.

Bynum did not think more about it until investigators called him much later. "I'd sold what I had by then," he said.

Last year in Miami, pharmacy inspectors visiting a wholesaler applicant found a backroom operation with "rags that reeked of lighter fluid," heat guns, $75,000 worth of drugs and a trash can containing labels from 21 Medicaid patients, according to state records. The application was denied. One of the 21 patients was Michael McKinnon, who in November pleaded guilty to selling drugs that had cost Florida Medicaid nearly $16,000. McKinnon, 43, was making $5,000 a month from the scheme, court records show.

That arrangement pales beside an ongoing case in Sacramento involving the growth hormone Serostim, which costs $6,700 a month. Court records document 300 participants and a $18.9 million loss to California Medi-Cal between 2001 and last April. The ring serviced bodybuilders, but then expanded into selling the drug back to pharmacies, investigators said.

The conspirators recruited patients at HIV clinics in Los Angeles and drove them to pharmacies. "Some of them dumped these guys off by the vanload," federal prosecutor Daniel Linhardt said.

The Trizivir sent to Renthal in Arizona started out on Feb. 11, 2002, with a patient from Lauderhill, Fla., according to records and interviews obtained by The Post. Florida Medicaid paid $967 for the prescription at Commcare Pharmacy.

The patient's bottle went to a ring that concocted paperwork making it appear the drug had moved through small wholesalers in Texas and New Hampshire, which investigators say were fronts.

The bottle then went to Albers Medical Distributors of Kansas City, Mo., which sold it on April 4, 2002, according to a complaint filed by the Missouri Board of Pharmacy. An Albers spokeswoman said she was unaware of the incident.

From Albers, the Trizivir went to ActSys Medical Inc. of Westlake Village, Calif., which sold it to Renthal in mid-April. ActSys President Kelly Smith later said his company was unaware that the drugs had come off the streets. "It was eye-opening," he said. "It showed us some cracks in the system."

Renthal recalled being offered the drug for "about $50" less than the usual $1,100. She went with the small supplier, who was not her regular source, "because the marketing was so good. Lots of phone calls, mailings."

But when the drugs arrived, they bore a label showing they had been sold to the Florida Medicaid patient.

All of Renthal's Trizivir was returned to Florida, where inspectors concluded it came from the streets and was cleaned with lighter fluid.

In July, Florida prosecutors indicted 18 people and charged them with operating a huge racketeering ring that dealt in stolen, counterfeit and adulterated pharmaceuticals, including the Trizivir that went to Renthal.

Renthal called the Fort Lauderdale pharmacist who filled the prescription. "He acted like I was stupid for not knowing this type of thing goes on," she said.

"It isn't shocking to me," the pharmacist, Sal Saraniti, told The Post. "If you can't make your rent and don't have money but have a prescription worth 900 bucks or more that you can sell for $100 or $200, that's a lot of money you can get right away."

washingtonpost.com

Nevada Gets Tough, With Mixed Results

By Mary Pat Flaherty and Gilbert M. Gaul
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RENO, Nev. -- In 2001, Nevada adopted the tightest controls in the country for pharmaceutical wholesalers in an attempt to combat a growing illegal trade among tiny wholesalers that diverted and resold millions of dollars' worth of steeply discounted drugs. Over more than a decade, wholesalers had set up shop in Las Vegas, occupying an entire block in one industrial neighborhood.

The new measures required owners to employ an authorized representative with 6,000 hours of experience, and strictly limited resales to other wholesalers to 10 percent.

The regulators' efforts worked. Over the next two years, the number of wholesalers plummeted from 50 to eight, as distributor after distributor declined to renew its license with the Nevada State Board of Pharmacy.

But Nevada's efforts offer an object lesson in the difficulty in policing the growing shadow market in pharmaceuticals. When the Nevada regulators took action, some wholesalers simply moved operations across the state line into California. Recently, several wholesalers sued Louis Ling, the board's general counsel, and Keith Macdonald, its executive secretary, alleging that the officials impeded their business.

Nationwide, attempts at changing the pharmaceutical distribution system have been hit-and-miss. A federal law requiring more complete sales records on medications sold among wholesalers has been on hold since 1988. The regulations to implement that law, the Prescription Drug Marketing Act, have been delayed four times by the Food and Drug Administration.

A strong federal law or model legislation drafted by a government-industry task force and adopted by the states could standardize controls over distribution of pharmaceuticals, said Marvin Shepherd, a researcher in pharmacoeconomics at the University of Texas. So, too, would tougher rules on pedigree papers, the documents that are supposed to track sales of a medication as it passes among wholesalers. Those records would give regulators clout to pursue violators, he said.

If that paperwork went to retail buyers, they could be more certain about the products they were getting, Shepherd said.

In California, the pharmacy board is examining a number of proposals to tighten licensing and regulation of its 400 pharmaceutical wholesalers, said Patricia Harris, the board's executive officer. For years, the board has struggled to keep up with small, rogue wholesalers that buy steeply discounted drugs intended for nursing homes and divert them into the shadow market.

"The problem is they have no records," Harris said. "There is no way of tracking, no documentation. When we walk in, drugs are missing, and we have no way of knowing where they've gone."

One of the California board's proposals is modeled after Nevada's changes. It would limit the number of times wholesalers can sell to other wholesalers before the drug is sold to a retail chain. Another would allow the board to levy as much as $5,000 in fines each time a wholesaler violated a law, providing

"economic teeth," Harris said.

Two years ago, the board adopted similar economic sanctions for Internet pharmacies, with fines of as much as $25,000 per incident for dispensing dangerous drugs online. In May 2002, the board issued citations against a Los Angeles Web site and two pharmacists that included $88.7 million in potential fines. As part of a settlement with the board, the online pharmacy recently agreed to pay a $1 million fine.

When Florida announced in 2001 that it would begin enforcing a pedigree-paper law, and then said it would go further and require that buyers verify the accuracy of the paperwork, "that hit a nerve more than anything I've seen in the 17 or 18 years I've been doing this," said Gregg Jones, a Florida pharmacy investigator.

After several delayed implementations, Florida this year passed tougher criminal penalties, elevating the falsification of pedigrees to a felony. But other tougher suggestions recommended by a special Health Department committee were put on hold.

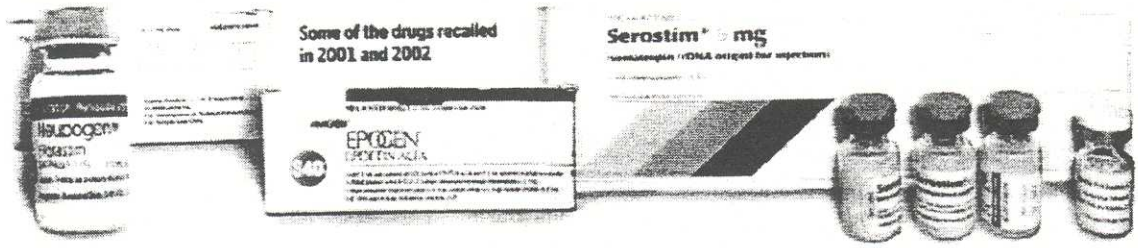
The Health Department had suggested requiring pedigrees for all drugs. The industry objected to the full pedigree. The industry also opposed having it apply to an estimated 30,000 drugs. Industry lobbyists said the rules would drive wholesalers out of Florida and cost the state jobs and revenue.

Florida's legislation, which took effect this past July, toughened background checks for wholesalers. But full pedigrees were required for only 30 drugs.

Counting Counterfeits

The nation's Big Three pharmaceutical wholesalers say all but a small percentage of the products they sell come directly from manufacturers, which severely limits the chance for counterfeits and tampered products to get into the national distribution system. Customers of the Big Three include major hospitals, national drugstore chains and mail-order pharmacies that fill prescriptions for many employee health plans. Yet since 2000, the Big Three—AmerisourceBergen of Pennsylvania (the product of the merger of Amerisource and Bergen Brunswig Drug Co.)—McKesson of California and Cardinal Health of Ohio (which merged with Bindley Western) have discovered these counterfeits in their warehouses, medicines that federal and state records show were purchased from smaller wholesalers for sale nationwide.

Drug	Quantity	Notification date	Distributed	Company
Retrovir	52 bottles	August 2000	Unknown	Amerisource
Serostim	9,998 vials	March 8, 2001	Calif., Hawaii, Tex., Wash., Md.	Bergen Brunswig Drug Co.
Neupogen	Unknown	July 24, 2001	Ky., Ark., La., Tenn., Miss., Ala., Mo.	AmerisourceBergen
Epogen	16,110 vials	May 17, 2002	Unknown	AmerisourceBergen
Procrit	53,888 vials	June 3, 11, 2002	Unknown	Bindley Western
Serostim	1,750 vials	August 2000-April 2001	Unknown	McKesson



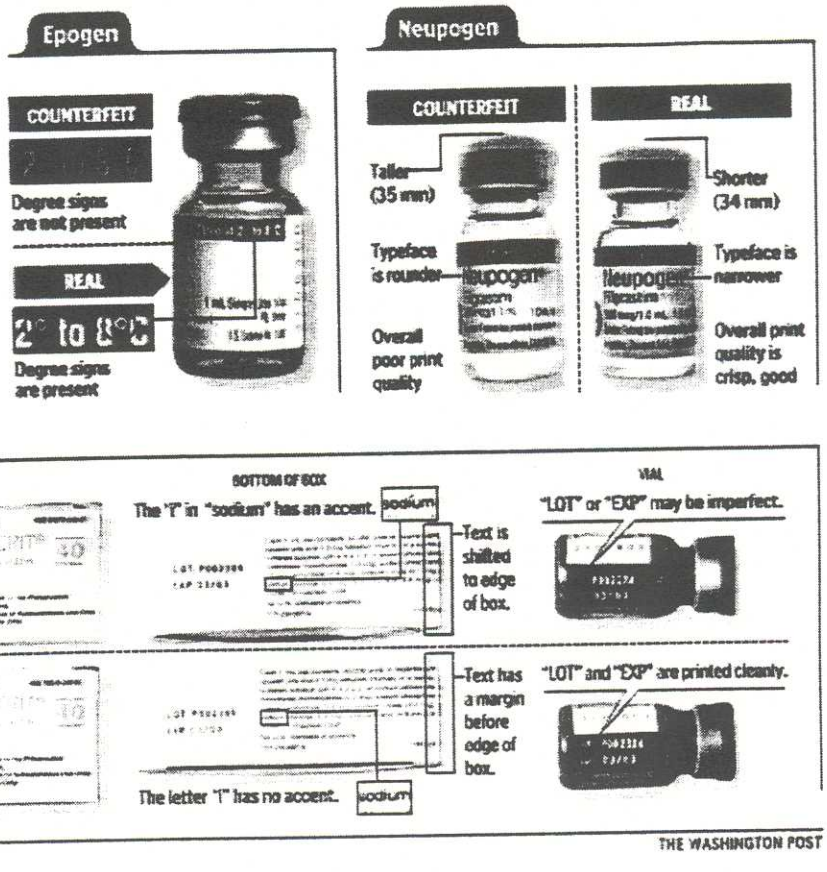
NOTE: Because manufacturers are not required to report counterfeits to the Food and Drug Administration, this list may not reflect all of the counterfeits that made it to the large wholesalers and does not reflect other major recalls, including one this summer of nearly 200,000 bottles of counterfeit Lipitor.

SOURCE: Food and Drug Administration, manufacturers' notices, Florida Department of Health (Retrovir), Nevada State Board of Pharmacy (McKesson)

THE WASHINGTON POST

Finding the Fakes

Counterfeiting of expensive and exotic new drugs has become so accurate that a tiny printing error may be the only tip-off that a product is fake.



washingtonpost.com

Millions of Americans Look Outside U.S. for Drugs

Desire for Low Prices Often Outweighs Obeying Law

By Mary Pat Flaherty and Gilbert M. Gaul
Washington Post Staff Writers
Thursday, October 23, 2003; Page A01

Fifth of five articles

PORT OF ANDRADE, Winterhaven, Calif. -- William Brooks has a good job and good prescription drug benefits. He also has rosacea, a skin ailment he treats with an ointment. His employer's health plan picks up most of the cost, leaving him to pay only $14 when he fills his prescription.

But Brooks said he can buy the ointment for $6 -- and does -- "over there," jutting his thumb toward the narrow road into Los Algodones, Mexico, a few hundred feet away. "I seem to be getting the same thing," he said.

Brooks, 48, is one of millions of Americans who have turned to Mexico and other countries in search of bargain drugs.

What makes him different is this: He is the director at the Andrade port of entry for the U.S. Bureau of Customs and Border Protection, in charge of stopping prescription drugs from illegally entering the country.

The port director embodies a national contradiction: Although U.S. law bans nearly all imports of foreign medications, Americans are bringing in those drugs in record numbers.

Mexico, Canada and other countries have become the discount pharmacies for many Americans, those looking simply to save money as well as the uninsured struggling to pay for their medications.

In the process, the nation's drug distribution chain is being breached, exposing consumers to risk and swamping regulators, according to state and federal records and interviews with dozens of federal agency officials, state investigators, academics and security specialists for the pharmaceutical industry.

Customs estimates 10 million U.S. citizens bring in medications at land borders each year. An additional 2 million packages of pharmaceuticals arrive annually by international mail from Thailand, India, South Africa and other points. Still more packages come from online pharmacies in Canada.

At peak season at Andrade, when snowbirds flock to the desert crossing west of Yuma, Ariz., 13,000 people a day return from Mexico, "and nearly everyone has medications," Brooks said. "The pharmaceuticals are absolutely the draw." In northern Mexico, *farmacias* edge out strip joints and cantinas on many of the main drags.

At San Ysidro, Calif., which abuts Tijuana, Mexico, 90 million people a year cross, leaving inspectors there with an average of five seconds to size up what travelers may have in their packages, supervisory inspector Joseph W. Misenhelter said. "Medications are only one of our concerns."

At the Washington Dulles International Airport mail site, between 10 and 15 tractor-trailer loads of

international parcels arrive daily. Enforcement agents who peer through X-ray scanners and scour labels looking for pills and vials are "pulled a lot of ways," with terrorism -- not illegal pharmaceuticals -- as their first priority, Dulles chief inspector Hal Zagar said.

The Food and Drug Administration said that nearly all of the medications brought in from foreign sources by individuals are illegal and possibly unsafe. But agency officials have said they do not want to be the ones seizing medications from seniors. Customs and border inspectors who are the frontline enforcers of federal law allow in most pharmaceuticals, because "we are not in the business of taking away medication from people who need it," as Brooks said.

The debate over allowing Americans to take advantage of cheaper drugs from overseas has been a recurring battle in Congress for the past three years. Proposals have ranged from allowing imports from about 30 countries to allowing them only from Canada. That debate continues, with the issue of opening the borders now linked to the question of whether to add a prescription drug benefit to Medicare.

As those congressional debates continue, however, many Americans have reached their own decisions, buying foreign medication pill by pill and package by package.

Top FDA officials say sheer volume makes inspecting every package at the border or in the mail impossible. Customs inspectors set aside packages that appear to be medications so an FDA inspector can decide whether they can be released to the buyer. But the agency does not have inspectors on site every day, even at large border crossings and mail facilities.

In 2001, the FDA proposed that all medication mailed into the United States be returned to its sender, except for a fraction that doctors could import for gravely ill patients. The proposal went in a memo to Health and Human Services Secretary Tommy G. Thompson. Two years later, the memo remains unanswered.

The FDA is trying to develop strategies to assess risks and identify prime targets for enforcement. "We can't win this playing man to man," FDA Commissioner Mark B. McClellan said.

If the FDA decides to hold packages, citizens can appeal, a process that can take months and creates huge backlogs of stored medications. It also lands the agency at the center of an emotional debate on how to make medication more affordable.

"We get beat up," said William K. Hubbard, the FDA's senior associate commissioner. "It's more phone calls from the Hill. The politics of seniors drives the political issue and will for a while until we give people a way to get their drugs here."

Laura M. Nagel, deputy administrator of the Drug Enforcement Administration, is concerned about prescription narcotics and other controlled substances coming across the borders and by mail. She said she has "nothing but sympathy for these poor, lower-pay-grade customs inspectors who are becoming pharmacists as they work against the tide."

But after years of promises that the FDA would take action, Nagel's sympathy is at its end: "I want my law enforced."

Exception to the Rule

As the forces reshaping the U.S. drug distribution system come to bear on the country's gatekeepers,

"discretion" -- a word that Brooks and customs inspectors near San Diego and Laredo, Tex., all used -- has overtaken regulation.

U.S. officials draw a bright line at smuggled medications or obvious counterfeits or drugs that have been rejected for the U.S. market. But a traveler who has a prescription and buys no more than a three-month supply of medication for his own use will most likely be allowed in.

Even that allowance strays from the original 1954 regulation, revised in 1988, for travelers who bring in foreign medication. Known as the personal-use exemption, the 1988 revision came when AIDS was surging and domestic treatments were scarce. The FDA responded by saying that patients with life-threatening illnesses under a doctor's care could import a few months' worth of medications, even if the drugs were not approved in the United States.

But that exemption opened the floodgates. It rapidly became abused and misquoted by everyone from Congress members to Internet pharmacy owners who say anyone is entitled to bring in a three-month supply of any medication. In the absence of enforcement, foreign imports poured in. Today, the result is confusion.

The FDA's "lax" response to abuses of the personal importation exemptions coupled with the rise of the Internet has led to "a massive problem," said Benjamin England, a former regulatory counsel at FDA headquarters and 17-year veteran of the agency now in private practice in Washington.

"It didn't take long for someone to fill the opening that created, and now you've generated a whole market," he said. "By the time FDA recognized the problem, the economic engine was running wide open and it was out of their hands. They let it become a political issue because they didn't address it when they should have, and that's where they're stuck."

An incident this summer in Miami was "a real train wreck," England said.

In May, the FDA released nearly 2,140 mail packages of counterfeit Viagra that had been seized seven months earlier in Miami because they did not appear to be made by Viagra's manufacturer, Pfizer Inc., according to customs and FDA records. Samples from the packages, mailed from Belize, had been sent to the FDA for testing. In January, the lab concluded that some pills were less than full strength and others some were overly strong -- a more serious risk, given Viagra's side effects. Despite that information, the FDA headquarters released the packages to the U.S. customers who had ordered them. Some of the FDA's Miami staff questioned that decision: "Shouldn't we refuse entry particularly on a Rx drug like Viagra?" one wrote in an e-mail. The reply from a supervisor: "We released it because we do not have the resources to deal with mail entries."

The FDA headquarters has since said it made "a mistake" and sent letters to customers warning them that the agency could not vouch for the safety of the foreign shipment. But the FDA did not share with consumers what the lab tests had found, a copy of the letter shows. An FDA spokesman later said that the agency had sent a standard letter.

Since 2000, customs officials have asked the FDA for written guidelines on what ought to be held for FDA inspection. If the FDA will not ban virtually everything -- as current law demands -- what should customs stop?

Three times since 2000, FDA officials have testified they are preparing the answers. But written guidance has yet to come, Elizabeth Durant, director of trade programs for customs, told a congressional

committee this past summer.

"If FDA told us to just ship it back, we could ship it back," she said.

In addition to the personal-use exemption, regulators struggle with another loophole.

The DEA is moving to close an opening through which painkillers and other controlled substances cross U.S. land borders. Since 1970, travelers who obtained a prescription narcotic abroad -- presumably for a medical reason -- were allowed to bring it home without a U.S. prescription. In 1998, to stop widespread abuse, the law was amended to limit a traveler crossing from Mexico or Canada to an amount less than "50 dosage units" of any given drug.

Some travelers just shifted to carrying in their drugs in increments of 49 doses apiece.

"An exemption for legitimate travelers has got bastardized," said Elizabeth A. Willis, chief of drug operations for the DEA. The DEA now is proposing a limit of 50 doses total per trip -- a change that would cut but not eliminate the traffic, Willis acknowledged.

Americans Invade Mexico

Hugo Moreno, all pumped-up chest and wraparound sunglasses, flashes a dazzling smile and tilts his chin: "What are you looking for? We'll have it. C'mon over, look at these prices."

He works the sidewalk in front of the "Purple Pharmacy," as the big shop directly across the border in Los Algodones has come to be called by American customers who cannot manage its proper name, "Pharmacia Liqui's."

With his running patter, Moreno, 23, has undeniable curb appeal, slinging jargon he picked up at college in Arizona, winking to the men as he points out the Viagra prices, bending down to boost an older woman with a cane from the street to the pavement.

"In there," he says nodding toward the clerks, "you need to know a little something about medicines. Out here," he says with a grand sweep of his arms, "it's all personality."

Not that Moreno would have to work hard. Americans flock here.

Even on a slow June morning, license plates from throughout the Southwest, Midwest and West could be seen on cars whose doors opened to let out gaggles of white-haired men and women. Trunks popped to release canes, walkers and at least one portable oxygen tank -- every bit of that equipment summoned to aid an older person in a slow and deliberate walk to Los Algodones's pharmacies.

Painted as purple as Barney, Liqui's is anything but subtle. A sandwich board posts prices for hot brand names -- Lipitor, Fosamax, Premarin, Captopril -- that translate into a list of maladies hitting older Americans: high cholesterol, osteoporosis, menopausal effects, heart failure. Sheets of paper -- 144 in all -- curtain the store's front windows, each one an "especial."

Inside, bottles of drugs sit in glass cases. Many are generics, some made in Mexico, others repackaged in Mexico with their manufacturing site not apparent. Others, with Spanish labels, say they were made in Germany or Panama.

Medications, including bottles labeled as the blood thinner Coumadin -- which requires a prescription in the United States and regular blood testing to monitor dosages -- could be bought off the shelf.

Dick Kujawa, 63, and his daughter, Dee Blake, of Mesa, Ariz., studied the prices. A recently retired warehouse worker, Kujawa lost prescription drug coverage when he shifted onto Medicare. His daughter and her husband run an Internet-based business, "and don't have health insurance because it's so high for self-employed people," she said.

She was shopping for an antibiotic. Her father takes medications for high cholesterol, high blood pressure and heart failure. His drug bills run about $700 every three months, he said. A sign offering Zocor, a cholesterol medicine, caught their attention. At about $28 for 30 pills, each 80 milligrams, that cost would be half what he pays in the United States, he said.

"That's worth the trip, even if it is the generic," he said. Guessing whether a drug is the same might not be the best system, he said, but "it should be embarrassing to our country that we have to come down here for medicine, period."

Inside the Purple Pharmacy, Virginia Plowman, 65, of Mesa scanned the list of medications in her hand, some hers, some from friends. Until she turned 65 and had to rely on Medicare, she "didn't think about drug costs. I always had insurance."

The price for Zetia, another cholesterol-lowering drug, disappointed her. At $31 for 20 pills of 10 milligrams, it cost more than the $50 she paid at home for 90 pills. But she had already seen savings on Prilosec and Celebrex that she was considering but was determined to shop around "since that's what I'm here for."

While Los Algodones retains a rustic air, the main street of Tijuana has converted to a veritable medication mall. The painted burros are still there for tourist photos and so are the leather stores. But along a street once thick with strip clubs and bars, *farmacias* dominate, with "we have English" and signs for "smoothees" jostling signs for menopause medication.

Ignacio Romo, head of the pharmacists association in Tijuana known as Union de Farmacias y Boticas de Tijuana, winces at the explosion of pharmacies along Revolucion Avenue. Romo, who has run one small drugstore in a Tijuana neighborhood since 1951, said "it's become anarchy" along the avenue. Speaking through an interpreter, he said he worries "the professionalism of pharmacists is being degraded" by shops that post clerks in medical coats but offer no real expertise. "Just because you dress like a nun doesn't make you one," Romo said.

Elsewhere in Los Algodones and Tijuana, doctors were offering to write prescriptions for controlled substances in exchange for $20 or $30, no medical exam needed. A pharmacy in Los Algodones had preprinted and signed prescription pads on hand to give to American buyers in case they were challenged at the border. Another pharmacy in Los Algodones sold an American a generic antibiotic that was unapproved in the United States. A clerk in white coat packed it in a baggie and suggested the American hide it in a pocket to get it past customs.

In both towns were American shoppers who insisted they were saving at least half on drugs they need for chronic illnesses. Joyce Ernst, 65, of Las Vegas looked over the pills offered for sale and scanned the Physicians' Desk Reference, confident she could tell by sight if they matched the drugs she bought back home.

She decided against a full complement of Pariet, a treatment for stomach ulcers, because the pills looked slightly different. She bought just seven tablets to alternate those with her U.S. medicine "as a test. It's worth a shot." She bought Xenical, which aids in weight control, because at $90 it was $30 less than what she had paid the previous month at her drugstore -- a bill she carried in her hand as she ducked in and out of the pharmacies lined nearly door-to-door along Revolucion Avenue in Tijuana.

washingtonpost.com

Canada Is a Discount Pharmacy for Americans

FDA Doing Little to Stop Cross-Border Trade in Drugs

By Gilbert M. Gaul and Mary Pat Flaherty
Washington Post Staff Writers
Thursday, October 23, 2003; Page A17

WINNIPEG, Manitoba

Billy Shawn was never much of a student. He barely survived high school, skipped college and spent most of the next two decades wandering around the globe in search of the perfect wave.

But the 45-year-old surfer was no slouch when it came to business. With a natural gift for marketing, he opened a Web site in October 2000 selling inexpensive Canadian drugs to American seniors. His instincts told him that regulators in the United States would look the other way.

"I knew their hands would be tied politically," he said. "That's what I counted on for our success: friction between them being regulators and being beholden to the politicians."

Shawn's instincts proved dead-on. Although officials from the Food and Drug Administration have repeatedly said that buying drugs from Canada is illegal and unsafe, the agency does little about the surging trade in cross-border prescriptions.

Shawn's Internet pharmacy, the Canadian Drugstore, or tcds.com, now has $55 million in annual sales. It is one of approximately 120 Canadian online pharmacies selling about $700 million worth of prescription drugs each year to Americans. The drugs being sold are not narcotics, but are for such conditions as heart problems, arthritis and high cholesterol. In Manitoba, a rural province in the Canadian heartland and a hotbed for Internet drugstores, sales to American seniors now outpace the provincial health program's drug budget, according to interviews and records.

A combination of new technology, regulatory gaps and a growing demand for low-cost drugs is reshaping the U.S. drug distribution chain and fueling an entire new industry in cross-border prescription sales.

In effect, Canada has become the United States' favorite drugstore for seniors -- and its de facto Medicare drug benefit.

In recent months, the issue has captured national attention, with debates in Congress, protests by seniors, threats by U.S. drug companies to curtail shipments to Canadian pharmacies and announcements by several state and local governments that they intend to use Canadian drugs for their employee health plans.

Yet while many applaud the Canadian drugs as a lifeline, the Canadian traffic poses new challenges for state and federal regulators and highlights loopholes in a U.S. system that prides itself on being the toughest in the world.

"By and large, most of the drugs coming in from Canada are coming in illegally," said FDA Commissioner Mark B. McClellan. The agency "doesn't have the resources to monitor and inspect each

and every drug shipment at the border," he said.

In fact, the FDA rarely looks, interviews and records show. Most shipments are simply allowed through.

For Canadians, the sales evoke unique paradoxes of their own. Rural provinces such as Manitoba welcome the jobs and tax revenue generated by the Internet pharmacies. But Canadian officials worry about potential drug shortages and a backlash if U.S.-based drug manufacturers raise prices.

"I don't think the [Canadian] drug laws were intended to benefit Americans' shopping on the Internet," said Barbara Wells, head of the National Association of Pharmacy Regulatory Authorities in Ottawa.

Drug prices are low in Canada for two reasons: the weaker Canadian dollar and price breaks from pharmaceutical companies negotiated by the Canadian government in return for patent protections.

The Internet pharmacies trade on those discounts, buying cheaper drugs intended for Canadians and reselling them at a profit in the high-priced U.S. market.

"We knew we had great margins," said Shawn, whose Toronto-based Web site started with a handful of workers and now has 150 employees. "There was a price in the U.S. and a price in Canada. We could create a price somewhere in the middle that makes your customer happy, you make money and everybody wins."

Charles Specht, 62, a retired county worker who lives near Pittsburgh, began buying online from Canada in 2002 to save on his heart and blood pressure medications. Specht said he takes as many as 12 pills a day. By importing his medicines from Canada, he slashed his costs for a three-month supply from $600 to $350.

Such price disparities are not unusual, economists said. Prices vary from country to country depending on economies and government rules. In the United States, drug companies are able to charge more because they do not face a single government buyer able to bargain down prices.

"Private insurers are weak in the U.S., which is what the pharmaceutical industry wants," said Uwe Reinhardt, an economics professor at Princeton University. "There are all of these insurers, each with very little market power. . . . That is the reason why the U.S. pays the highest prices."

Spokespeople for pharmaceutical companies said prices are higher in the United States in part because Americans are picking up a greater share of expensive research. The drug companies also questioned the safety of the drugs being imported from Canada.

"People assume Canadians look an awful lot like Americans," said Chris Viehbacher, president of GlaxoSmithKline's U.S. pharmaceutical operations. "Therefore, if Canada approves something, it must be the same. In fact, each government puts in different [safety] regulations."

In January, Glaxo, the world's second-largest pharmaceutical maker with revenue of $31.8 billion, announced that it would curtail shipments to Canadian wholesalers supplying the Internet pharmacies. Several other companies quickly followed suit. Unruffled, the Internet operators have turned to loose networks of pharmacies scattered across Canada to augment their supplies.

"It really hasn't had much effect," said Kris Thorkelson, owner of CanadaDrugs.com, a Winnipeg-based Internet pharmacy with annual sales of $100 million.

Andy Troszok, vice president of the Canadian International Pharmacy Association, a trade group, criticized the U.S. firms. "We account for less than one-half of 1 percent of their sales," he said. "So it isn't because of our size. Basically, I think we've embarrassed them and drawn attention to their huge profits."

The growing market for cheap Canadian drugs has also spawned U.S.-based brokers who help to arrange cross-border prescriptions. Brokers such as Cheryl Gaddie of Thief River Falls, Minn., help seniors fill out paperwork and compare prices online. They then steer their clients to Canadian pharmacies that pay the brokers for the business.

Gaddie's Canada HealthCare Discount Centre, located in the foyer of a large medical clinic, receives 10 percent of the sales she directs to Drake Pharmacy in Winnipeg. The business started out slowly but is now generating more than $70,000 in sales a month, she said. During a visit last February, several elderly customers braved sub-zero temperatures to place their orders.

"I'm not getting rich on this, but there is a steady demand," Gaddie said.

In a few years, the number of brokers has swelled to several hundred.

Earlier this year, the FDA sent warning letters to a number of brokers, saying that they were facilitating the illegal importation of prescription drugs. This month, the Justice Department sought to get an injunction to temporarily close Oklahoma-based Rx Depot, which operates 85 storefronts nationwide. The case is pending.

"They know they can't go after the senior citizens directly," said Carmen Catizone, executive director of the National Association of Boards of Pharmacy. "They feel these guys [brokers] are commercialized and nobody really cares if they put them out of business."

If drug companies continue to squeeze the supply to Canadian Internet pharmacies, Troszok said, Americans will turn to online pharmacies in other countries "where counterfeiting is huge and the regulatory systems are far less rigorous."

For the moment, Americans are turning to Canada for brand-name drugs, not cheaper generics.

At Thorkelson's CanadaDrugs.com., shelves of popular American brand drugs, including Lipitor, Fosamax, Vioxx and Nexium, fill the cavernous 9,000-square-foot space in an industrial park across the railroad tracks from downtown Winnipeg. The company does carry some generics, Thorkelson quickly points out, but Americans appear "to prefer brand names."

Thorkelson said demand is driven by multibillion-dollar advertising and marketing campaigns financed by U.S. drug companies. "It increases our sales. No question about it," he said.

He said he and his colleagues know they skirt U.S. law. "We're completely aware," he said. "We've been aware from when we started. From our perspective, it's legal because American authorities aren't enforcing the strict reading of FDA regulations."

Across the prairie, in the tiny farming community of Minnedosa, RxNorth.com, an online pharmacy with sales of more than $40 million annually, has transformed the local economy. The Web site went from selling Nicorette gum to a full menu of drugs, moving from a storefront into a warehouse. With about 200 employees, the company is now the largest employer in town.

"If you are unemployed in Minnedosa, it's because you choose to be," said Pat Graham, the former head of the Chamber of Commerce, who once worked for RxNorth.

Today, there are 60 Internet pharmacies spread across the province, employing upward of 1,500. "For a small jurisdiction, that's very significant," said Maryann Mihychuk, Manitoba's minister of Industry, Trade and Mines. "It's a very dynamic new niche . . . and I am proud to back it."

Not everyone is as enthusiastic.

In February 2001, the Ontario College of Pharmacists swooped down on Billy Shawn's Toronto office and confiscated computers and paperwork. Shawn was fined for technical violations of the law and later agreed to pay a $20,000 fine and donate $125,000 to the University of Toronto Pharmacy School.

Shawn rebuilt his business, offering discounts of as much as40 percent on Lipitor and other popular drugs. The wave of Americans soon returned.

Cross-Border Drugs

An estimated **120-150** **Canadian online pharmacies** were in business in 2003, up from **4** in 1999.

Of those, **six** account for about **80 percent** of the **cross border sales.**

The province of **Manitoba** has about **60** online pharmacies, **About half** of all Candian online pharmacies.

U.S. customers bought an estimated **$700 million** from Canadian online pharmacies in 2002, up from about **$14 million** in 1999.

Manitoba-based online pharmacies accounted for estimated **$280 million** of those U.S. sales in 2003.

By comparison, the **Manitoba's provincial health program** spent about **$200 million** for outpatient drugs.

NOTE: All currency expressed in U.S. dollars

SOURCE: Manitoba Pharmaceutical Association, internet pharmacies, Canadian International Pharmacy Association

THE WASHINGTON POST

Attachment D

Board of Pharmacy
Proposed Additions
Title 16 - California Code of Regulations

1784. Wholesale Drug Transactions

(a) A wholesaler shall generate an invoice for each sale, trade or transfer of a dangerous drug or a dangerous device. The invoice shall include the lot number of the dangerous drug or dangerous device.
(b) A dangerous drug or dangerous device may only be sold, traded or transferred three times before being furnished to the final consumer. A wholesaler shall implement procedures to reasonably ensure that it does not sell, trade, transfer or purchase dangerous drugs or dangerous devices that have been sold, traded or transferred in violation of this section.
(c) The sale, trade or transfer of a dangerous drug or dangerous device between licensees with the same ownership are not subject to subdivision (b).
(d) Subdivision (b) shall not apply to expired dangerous drugs or dangerous devices or to dangerous drugs and dangerous devices that have been returned after they have been dispensed.

1785. Pharmacy Drug Transactions

A pharmacy shall may only sell a dangerous drug or dangerous device to a patient pursuant to a prescription, to the wholesaler that sold the dangerous drug or dangerous device to the pharmacy, or to another licensee with the same ownership.

Board of Pharmacy
Draft Changes for Wholesale Violations
August 22, 2003

Add Section 4168 to the Business and Professions Code, to read:

4168. (a) No person or entity shall:

(1) Purchase, trade, sell or transfer dangerous drugs or dangerous devices at wholesale from a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell or transfer counterfeit drugs or devices.

(3) Purchase, trade, sell or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(4) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to a fine of up to five thousand dollars ($5,000) per occurrence pursuant to a citation issued by the board.

(c) For notifications made on and after January 1, 2005, the Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

Attachment E

Board of Pharmacy
Prescriber Dispensing Reform
Concept Draft – September 16, 2003

4170. (a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

(1) The dangerous drugs or dangerous devices are dispensed, by the prescriber, to the prescriber's own patient. A registered nurse may hand to the patient the dangerous drugs or dangerous devices dispensed by the prescriber. ~~, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.~~

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).

(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice. This disclosure shall include information relating to the availability of generic drug alternatives and a statement that the drugs dispensed may be available at lower cost through purchase at a pharmacy.

(8) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or a physician assistant who functions pursuant to Section 3502.1, may ~~hand~~ furnish dangerous drugs or dangerous devices to a patient. ~~of the supervising physician and surgeon a properly labeled prescription drug, prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.~~

(b) The Medical Board of California, the State Board of Optometry, the Dental Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) "Prescriber," as used in this section, means a person, who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice dentistry, or a certificate to practice podiatry, and who is duly registered as such by the Medical Board of California, the State Board of Optometry, the Dental Board of California, or the Board of Osteopathic Examiners of this state.

Article 13 – ~~Non-Profit or Free~~ Clinics

4180. (a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a prescriber ~~physician~~, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.

(G) A group practice.

(2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of seven years for inspection by all properly authorized personnel.

(b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. Each license shall be issued ~~to a specific clinic and~~ for a specific location.

(c) For the purposes of this article, "group practice" means more than one prescriber operating a practice providing health care services at a specific location.

(e) Prescribers in a group practice shall maintain the following information for each prescription on file and this information shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing prescriber.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label.

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing prescriber.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(f) This section shall not apply to an individual prescriber practicing at a licensed location who dispenses drugs from the prescriber's personal stock of dangerous drugs and dangerous devices only to the prescriber's patients pursuant to Section 4170.

4181. (a) (1)Prior to the issuance of a clinic license authorized under Section 4180 (a)(1)(A) – (F), the clinic shall comply with all applicable laws and regulations of the State Department of Health Services relating to the drug distribution service to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(2) Prior to the issuance of a clinic license authorized by 4180(a)(1)(G), the group practice shall

comply with all applicable laws and regulations relating to drug distribution to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist and the professional director of the group practice.
(b) ~~These~~ The policies and procedures required by this section shall include a written description of the method used in developing and approving them and any revision thereof.
(c) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4182. (a) Each clinic that makes an application for a license under Section 4180 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.
(b) The consulting pharmacist shall certify in writing at least twice a year that the clinic is, or is not, operating in compliance with the requirements of this article. The clinic shall maintain these written certifications in the clinic for at least three years. ~~, and the most recent of those written certifications shall be submitted with the annual application for the renewal of a clinic license.~~
(c) For the purposes of this article, "professional director" means a ~~physician~~ prescriber acting in his or her capacity as ~~medical~~ professional director.

4183. No clinic dispensing drugs pursuant to this article shall be eligible for any professional dispensing fee that may be authorized under the Medi-Cal program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

4184. ~~No Schedule II controlled substance shall be dispensed by the clinic. This limitation shall not be construed to prohibit a physician dispensing a Schedule II drug to the extent permitted by law.~~ Clinics that dispense Schedule II and Schedule III controlled substances shall report those prescriptions to the CURES program pursuant to Section 11165 of the Health and Safety Code.

4185. The board, and any other authorized officer of the law, shall have the authority to inspect a clinic at any time in order to determine whether a clinic is, or is not, operating in compliance with this article.

4186. (a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug delivery system is ~~being~~ used.
(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for

potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.
(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.
(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.
(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.
(f) The pharmacist operating the automated drug delivery system shall be located in California.
(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.
(h) For purposes of this section, an "automated drug delivery system" means a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

4187. (a) Notwithstanding any other provision of law, an automated drug delivery system located in a clinic licensed pursuant to Section 4180(a)(1)(G) shall be owned and operated by a licensed pharmacy.
(b) Notwithstanding any other provision of law, a pharmacist may supervise a single pharmacy technician at a remote location where an automated drug delivery system is operated in a clinic licensed pursuant to Section 4180(a)(1)(G), and this pharmacy technician shall not be subject to the ratio established in Section 4115.

STATE OF CALIFORNIA -- STATE AND CONSUMER SERVICES AGENCY GRAY DAVIS, Governor

Consumer Affairs

MEDICAL BOARD OF CALIFORNIA
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August 26, 2003

Patricia Harris
Executive Officer
Pharmacy Board of California
400 R Street
Sacramento, CA 95814

Dear Ms. Harris: Patty

Thank you for sharing the draft proposed language that would modify existing law as it relates to prescriber dispensing of pharmaceuticals. Dr. Steven Rubins and Ms. Lorie Rice, Members of the Joint Task Force on Prescriber Dispensing representing the Medical Board of California, have had the opportunity to review this language and wish to provide their observations. First, it is their belief that this language substantially achieves the goals that the Task Force set out in its meeting of May 27, 2003. Specifically, the addition of proposed Business & Professions Code Section 4180, (G) A group practice, addresses the need to recognize the advantages to patients of making pharmaceuticals available in the modern medical office. They wish to express their appreciation for the work that you have done to bring this issue so far along.

As the Board of Pharmacy's Enforcement Committee considers the language that you have prepared, the Medical Board wishes to offer the following observations:

1. Current law requires physicians to maintain a drug log and a competent medical record that enables the auditing of their dispensing and management of pharmaceutical products within their practice. Your proposed language [Section 4170(d)] would add new specifics to that requirement that would apply not only in the group practice environment that was discussed at the Task Force meeting, but to all physicians who dispense drugs in their practice. Since the need for these enhanced record-keeping requirements was not a matter of extensive discussion before the Task Force, the Medical Board is not certain what problem has been identified with the current practices of independent prescribers that is being addressed by this language. We are concerned that adding new requirements for every physician, in the absence of an identified problem, is unnecessary and will make passage of a proposed bill problematic.

2. The proposed definition of a "group practice" [Section 4180(c)] suggests that all physicians who are affiliated with a group practice must manage their dispensing practices through the standards established in Section 4182(a)(2). In reality, some

physicians who participate in a group practice may not wish to affiliate with other members of that practice as it relates to dispensing procedures. In the event that a single physician in a group practice chooses to manage their dispensing practices independently, we propose that this be accommodated by addition of the following sentence to 4180(c): This section shall apply only to those licensees of the group who also participate in the dispensing practices of the group.

We would also like to raise some additional considerations that may call for clarification through additional language. The first matter relates to some confusion that may be created by Sections 4170(a)(1) and 4170(a)(8). Section 4170(a)(1) states that a nurse or physician "attendant" may not furnish dangerous drugs. Section 4170(a)(8) says that a nurse or a physician "assistant," operating under standardized procedures, may hand prescription drugs to a patient. It is unclear whether the physician attendant is a classification different than that of physician assistant under the law, and if there is a legal distinction between the words furnish and hand. We believe that, over time, these have taken on a common meaning, but there may now be an opportunity for us to provide greater clarity in the law. This becomes important because the modern medical practice recognizes the great range of supportive services that are performed by nurses and physician assistants under standardized procedures. These services can include providing pre-packaged drugs to a patient and patient consultation designed to improve compliance with treatment objectives. This aim is further supported in your proposed Section 4181(a)(2). Therefore, it is important that physicians know precisely the scope of responsibilities that can be delegated to these personnel under written protocol.

The second issue that we would raise for your consideration is to emphasize that a consumer should ultimately be both safeguarded and provided an advantage by the expanded dispensing options that are being made available. Whenever the prescriber is also the seller of the product, it is imperative that the consumer realize that they have options available to them regarding whether or not to purchase the drug in the physician's office. Section 4170(a)(6) and (7) requires the prescriber to offer a written prescription and to provide written disclosure to the patient concerning that choice. We believe that this should be emphasized as well as strengthened. It is believed that this can be accomplished by amending Section 4170(a)(7) to add the statement: This disclosure shall contain information relating to the availability of generic drug alternatives and information that cost savings may be available through purchase at a pharmacy.

Thank you for your consideration of the views expressed in this letter. Ms. Rice, Dr. Rubins and I are available to discuss any of these issues further and look forward to working with you to implement the work of the Task Force.

Sincerely,

Ron Joseph
Executive Director

Attachment F

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Of Counsel: ALLEN D. EMMEL*

September 3, 2003

Enforcement Committee
c/o Patricia Harris, Executive Officer
California State Board of Pharmacy
400 R. Street, Suite 4070
Sacramento CA 95814

Re: Compounding Issues: Labels and Central Fill

Dear Enforcement Committee:

On behalf of several clients and the Compounding Pharmacist Section of the California Pharmacists Association, thank you for putting these issues on the agenda for the next Enforcement Committee Meeting.

1. Labels on Compounded Products.

An issue that has been brought to the attention of several compounding pharmacists involves the appropriate content of labels of compounded products. There is widespread agreement with the Board that current label requirements reflect information that is needed by consumers when they receive compounded products. The problem arises when the compounded product is provided in multiple units of a dosage form – i.e. suppositories, single dose vials, etc. – for which individual product labels are either not feasible, cost prohibitive or even a hindrance to treatment. For instance, many creams are dispensed in application syringes that contain multiple doses of the product. Graduations on the syringes are used to measure the individual dose. Because of their size, placing a label on each syringe would obstruct these graduations, making accurate dosing difficult or impossible.

The question raised is: What, if any, information does the Board feel should be included on individual units of compounded products that are dispensed to patients?

In the opinion of the pharmacists we surveyed, this should be a matter for the individual discretion of the compounding pharmacist. In many cases, individual doses should contain some sort of label to indicate the active ingredients. The form of this label will vary depending on the dispensing unit and available space. In other cases, a label on individual doses will result in little or no benefit and will cause more problems than it solves. In the case of compounded tablets and capsules, identification of any kind on individual doses simply isn't practical.

In any case, the patient should be made aware of the situation and advised to always keep the doses in the box, bag or container in which it was dispensed and which is labeled with the information that may be needed by a family member or emergency personnel in the event of a problem.

To clarify existing law and resolve any conflicts that may arise, we ask that the Board of Pharmacy weigh in on this issue. We welcome the opportunity to participate in a dialog to reach a reasonable and agreeable guideline for labels on compounded products.

2. Compounding in Central Fill Pharmacies

Many pharmacists and pharmacies are specializing in compounded products. The value of these products is broadly recognized. The Board's recent activities with regard to compounding of sterile injectable products has provided needed focus on the systems and facilities needed for the safe compounding of sterile injectables.

For a large number of compounded products, similar, if less stringent, systems and facilities are needed for the preparation of products to assure consistency in preparation and potency. Pharmacies that specialize in this practice have invested in those systems and facilities and, as evidenced by the growth in this area of practice, the products they compound are accepted as effective and safe.

We believe consumers should have improved access to compounded products. A safe and cost-effective way to accomplish this is to allow compounding pharmacies to act as central fill pharmacies for compounded products in the same way as is allowed for other prescriptions under CCR 1707.4. The Board has authorized similar activity for parenteral products for many years (cf B&P sec. 4123). We believe allowing central filling of compounded products under the provisions of 1707.4 will improve access for consumers, reduce costs and result in the provision of more consistent, safer and more effective compounded products.

We ask the Board to move forward on this proposal and are willing to work with the Board to resolve any problems that stand in the way of this application of section 1707.4.

I look forward to discussing these proposals further at the upcoming Enforcement Committee meeting.

Sincerely,

John Cronin

John Cronin, Pharm.D., J.D.

Attachment G

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

ENFORCEMENT COMMITTEE MEETING

Meeting Summary
September 17, 2003

Department of Consumer Affairs
400 R Street, Suite 4070
Sacramento, CA 95814

Present: John Jones, Chair and Board President
Stan Goldenberg, Board Member
Bill Powers, Board Member
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Joan Coyne, Supervising Inspector
Board of Pharmacy Inspectors
Ron Diedrich, Liaison Deputy Attorney General
Joshua Room, Deputy Attorney General
Enforcement Staff

Call to Order

Enforcement Committee Chair John Jones called the meeting to order at 9:30 a.m.

Reimportation of Prescription Drugs from Canada

Committee Chair John Jones stated that Senator Alarcon requested an opinion from the Attorney General on several questions regarding the importation of prescription drugs. Before issuing an opinion, it is the Attorney General's policy to solicit views of all interested parties.
The federal Food and Drug Administration (FDA) sent a letter to the Attorney General responding to the questions. A copy of the response was provided to the committee. In addition, the committee was given other articles on this issue and an overview prepared by the National Association of Boards of Pharmacy (NABP) that displays the informal and formal actions that state, federal, and other regulatory agencies have initiated against storefronts, pharmacies and other groups and individuals who facilitate or otherwise assist in the importation of prescription drugs from Canada.

Concern was expressed that the Board of Pharmacy had not taken a position on this issue. It was discussed that a private party may take action against a Canadian storefront for unfair business

practices and absent a position from the board may negatively impact the private party's action. Committee Chair Jones reiterated the board's position that the importation of drugs from foreign countries is a federal issue and within the purview of the FDA. California Pharmacy law specifies that the board's primary purpose is consumer protection. The board is concern that patients have access to safe prescription medications, and will investigate any consumer complaint that involves a prescription drug from Canada. He added that it is not the board's position to pursue complaints for economic or competitive reasons.

The board will continue to evaluate this issue and seek comments during its committee and board meetings.

Business and Professions Code Section 4343 – Prohibition of Pharmacy-Related Signage

Committee Chair John Jones explained that Business and Professions Code section 4343 establishes a prohibition on the use of signage that includes words such as "pharmacy," "drugstore," "apothecary," or words of similar import unless the premise is a licensed pharmacy. Although the board has never received a consumer complaint regarding the use of pharmacy-related signage, the law is enforced when the use of such signage may be misleading to the public. The board has been requested to enforce this provision against storefront facilities that assist consumers in obtaining prescription medications from Canada. It was discussed that the use of pharmacy-related signage in this instance is not confusing to the consumer.

It was noted that the origin of this prohibition was in 1905 that established a general regulation of pharmacists. It brought existing "pharmacies" by whatever name, under the board's regulatory authority. It was an inclusive statute designed to assert the board's jurisdiction over existing businesses. While over the years the law has been changed, the intent of this section has remained constant.

It was also discussed that the board has very little enforcement options because it is non-licensed entities that violate this section of law. Usually the only option is refer the matter to the local district attorney to file a criminal complaint.

The committee reviewed this issue on signage in response to the Governor's directive to evaluate the board's mandates to determine if they are necessary in light of the state's fiscal condition. The committee concluded that the law did serve a useful purpose and should be retained.

Proposed Citation and Fine Statute for Wholesale Violations and Proposed Regulations Regarding Wholesale Transactions

Chair John Jones reported that at the last Enforcement Committee meeting, Supervising Inspector Judi Nurse gave an overview regarding bid contract diversion in California. Pharmacies purchase "bid contract" drugs at special prices and then through a common ownership transfer the drugs to its wholesale facility to be resold to other wholesalers. Often times, there is no record for these drug transactions. The drugs are resold several times through many wholesalers and many states in largely undocumented transactions that are impossible to

trace. This "gray market" system has allowed for counterfeiting which is the dilution, mislabeling or adulteration of drugs. The unscrupulous companies can turn one shipment of injectable medications into many by watering down the drugs and reproducing the packaging.

The issue of bid contract diversion and the proliferation of counterfeit drugs have caused the committee to propose regulations to ensure the integrity of California's drug distribution system. The committee discussed the regulation proposal at its last meeting and comments were made that the regulation would impede legitimate business transactions and modifications were suggested. It was also stated that the federal PDMA allows for intra-company sales, which may be contrary to the proposal. While the board had been using Nevada as its model for the regulatory framework, it was suggested that the committee might want to review the Florida legislation. This new legislation identifies a list of drugs that requires due diligence in authenticating prior transactions on pedigrees.

Chair John Jones requested interested parties to submit proposed language to address the concerns that were discussed; however, none were provided. Therefore, staff prepared a new regulatory proposal to address wholesale and pharmacy transactions. In addition, a legislative proposal was prepared for citation and fine authority for wholesale violations. It was explained that the legislative proposal was intended to seek monetary sanctions for economic motivations for law violations. While the board can pursue cases administratively for these same violations, usually by the time any formal action is pursued, the wholesaler permit is cancelled and the board has no authority over the non-licensed owners.

There was considerable discussion regarding the burden that the proposed regulations would place on the wholesaler. Currently, drugs are not tracked by lot numbers and it would be unreasonable to limit the sale or transfer of a drug to three times prior to being furnished to the final consumer. It was unclear as to the magnitude of the problem and the committee asked staff to provide documentation at its next meeting in December before making a recommendation to the board.

Medical Board of California (MBC)/Board of Pharmacy Joint Task Force on Prescriber Dispensing

Committee Chair John Jones reported that the Medical Board of California (MBC) and the Board of Pharmacy held a joint task force meeting on the issue of prescriber dispensing. The meeting was held on May 27, 2003, and the task force reached consensus on the following: (1) Under current law, an individual prescriber can own his/her own prescription stock and dispense to his or her own patients as specified and such practice should be allowed to continue with the goal of strengthening and educating prescribers regarding the record keeping requirements; (2) Allow a medical group to dispense prescription medications pursuant to a special permit issued by the Board of Pharmacy and specified conditions that require one physician from the medical group to be responsible and accountable for the security of the prescription medications, record keeping requirements, and a consultant pharmacist reviews the dispensing process; (3) Establish the authority for a pharmacy to place an automated dispensing device in a prescriber's office; and (4) Provide for joint oversight by the appropriate licensing agencies.

The task force agreed that staff from the two boards would work together to draft language for each board to consider as a possible joint legislative proposal for 2004. Draft language was developed and the Medical Board task force members provided comments on the draft. The language was reworked to address their comments. The proposal would require a special clinic licensure for these group practices, which would have a fiscal impact to the board.

Concern was raised by interested parties that they had just received the proposed language and did not have sufficient time to review it and provide comment. There was also discussion that consensus was not reached on this issue contrary to the statement made by the task force. The Enforcement Committee agreed to discuss this issue at its December meeting so that the interested parties had sufficient time to review the proposal.

Medication Shortages and Limited Distribution Practices of Manufacturers and the Impact on Public Health

Board and committee member Stan Goldenberg requested that this topic be discussed at an Enforcement Committee meeting. His request was based on a Citation and Fine Committee's review of a consumer complaint regarding the inability of a pharmacy to fill the patient's prescription because the pharmacy didn't have the medication due to a manufacturer's shortage.

A patient had filed a complaint with the board against a pharmacy for not providing her with all the Enbrel that she was prescribed. The pharmacist only dispensed 4 kits instead of the 8. The pharmacist informed the patient that he was unable to fill her entire prescription due to a shortage of the medication. The patient was upset because she specifically had registered with the drug manufacturer to avoid such situations. The manufacturer assured her that they were sending the pharmacy her entire order. The patient felt that the pharmacy was giving her medication to other patients. In this specific case, the complaint was closed with no further action.

The committee discussed this issue and it was determined that these types of complaints should be handled on a case-by-case basis. If the pharmacist does not fill a prescription accordingly, then he/she is in violation of CCR, title 16, section 1716 (variation from a prescription). The board should not be involved in the contractual arrangement between the patient and the manufacturer.

It was noted that the National Association of Boards of Pharmacy (NABP) has appointed a task force to address this issue that is meeting in November.

Implementation of Enforcement Provisions from SB 361 (Pending)

Executive Officer Patricia Harris reported that SB 361 (Figueroa) is the legislative vehicle for the Board of Pharmacy sunset extension and contains statutory recommendations approved by the Joint Legislative Sunset Review Committee. Anticipating that the Governor will sign the

legislation, the following compliance provisions will be added to California Pharmacy Law effective January 1, 2004.

Section 4083 – Order of Correction

Would allow an inspector to issue an order of correction to a licensee directing the licensee to comply with the Pharmacy Law within 30 days by submitting a corrective action plan to the inspector or the licensee can contest the order of correction to the executive office for an office conference. If an office conference is not requested, compliance with the order does not constitute an admission of the violation noted in the order of correction and the order of correction is not considered a public record for purposes of disclosure. The licensee must maintain on the pharmacy premises a copy of the order of correction and corrective action plan for at least three years from the date the order was issued.

Add Section 4315 – Letter of Admonishment

Would authorize the executive officer to issue a letter of admonishment to a licensee for failure to comply with Pharmacy law, directing the licensee to come into compliance within 30 days by submitting a corrective action plan to the executive officer documenting compliance, or the licensee can contest the letter of admonishment to the executive office for an office conference. If an office conference is not requested, compliance with the letter of admonishment does not constitute an admission of the violation noted in the letter of admonishment. The licensee must maintain on the pharmacy premises a copy of the letter of admonishment and corrective action plan for at least three years from the date the letter was issued. The letter of admonishment would be considered a public record for purposes of disclosure.

Add Section 4314 – Issuance of Citations

Would allow the board to issue an order of abatement that would require a person or entity to whom a citation has been issued to demonstrate how future compliance with the Pharmacy Law will be accomplished and provides that such demonstration may include, but not be limited to, submission of a corrective action plan, as well as requiring the completion of up to six hours of continuing education courses in subject matter specified in the order of abatement.

Implementation of SB 151 (Pending)

Senate Bill 151 (Burton) repeals the triplicate prescription requirement for Schedule II controlled substance prescriptions and replaces it with a tamper resistant prescription form that may be obtained from approved printers. This new form will be required for all controlled substance prescriptions after a phase-in period. The bill also will require pharmacies to report Schedule III controlled substance prescriptions to the CURES system.

Because of the expansive nature of the changes required by SB 151, the new requirements will be phased in over a 12-month period. The following is a calendar outlining when the most significant elements of the bill become effective.

January 1, 2004

- The Board of Pharmacy (board) and the Department of Justice (Department) may approve security printers to produce the new controlled substance prescription forms.
- Permit mail order pharmacies to apply the prescription requirements of the state in which the patient resides when filling prescriptions.
- Controlled substance prescriptions (Schedules II-V) are valid for six-months.
- Requires all pharmacies to report Schedule II controlled substance prescriptions to the Department in a time and manner of the Department's choosing.
- Requires that Schedule III-IV controlled substance prescriptions be signed and dated by the prescriber.
- Controlled substance prescription forms may be acquired from approved security printers.
- Requires controlled substance prescription forms to have the following features:
  (1) Latent "void" protection so that if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
  (2) Watermark with the text "California Security Prescription" printed on the back of the prescription.
  (3) Chemical void protection that prevents alteration by chemical washing.
  (4) Feature printed in thermo-chromic ink (the ink changes color when exposed to heat).
  (5) Feature using micro printing (the text becomes a line if the prescription is copied or scanned).
  (6) Description of the security features included on each prescription form.
  (7) Quantity check off boxes printed on the form in the following quantities: 1-24, 25-49, 50-74, 75-100, 101-150, 151 and over.
  (8) Either of the following statements:
  (a) "Prescription is void if more than one controlled substance prescription is written per blank" or
  (b) Contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
  (9) The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.
  (10) A check box indicating the prescriber's order not to substitute.
  (11) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

July 1, 2004

- The Department may no longer produce or distribute triplicate prescription forms.
- Triplicate prescription forms may be used to prescribe Schedule II controlled substances.
- Prescribers may use the new controlled substance prescription forms for Schedule II controlled substance prescriptions.
- Oral and electronic orders for Schedule II controlled substance prescriptions for patients in skilled nursing facilities, intermediate care facilities, home health care programs, and

hospice programs are permitted. Such orders must be reduced to hard copy form and signed by the pharmacist on a form of the pharmacy's design.
- Requires prescribers dispensing Schedule II controlled substances to report those prescriptions to the CURES system.

January 1, 2005
- Triplicate prescription forms are no longer valid.
- All written controlled substance prescriptions (oral and fax orders for Schedules III-V are still permitted) shall be on controlled substance prescription forms.
- Pharmacies must report Schedule III controlled substance prescription information to the CURES system.
- Prescribers dispensing Schedule III controlled substances must report those prescriptions to the CURES system.

It was reported that the Licensing Committee reviewed the draft process for approving security printers at its September 10, 2003 meeting.

Prescription Requirements for Dispensing Non-Dangerous Drugs/Devices Pursuant to a Prescriber's Order for Medi-Cal Reimbursement

At its last meeting, the Enforcement Committee discussed a complaint that was received from a pharmacist via the California Pharmacists Association regarding the dispensing of medical supplies. During the inspection of this pharmacist's pharmacy in 2002, the inspector advised the pharmacist that since medical supplies require a prescription (for purposes of reimbursement), then the pharmacy is subject to the requirements of Business and Professions Code sections 4040, 4051 and 4076. These sections specify the requirements of a prescription, that only a pharmacist can dispense prescription items and prescription labeling requirements.

Currently legislation is pending, SB 857 (Speier) that would add section 14170.10 to the Welfare and Institutions Code that clarifies the prescription requirement for non-prescription items in order for providers to be reimbursed by Medi-Cal. In addition, CCR, title 22, sec. 51320, authorizes the coverage of medical supplies when prescribed by a licensed practitioner. These two provisions are consistent with the inspector's direction provided to the pharmacist in 2002.

Representatives from Medi-Cal explained that a prescriber's order is required for reimbursement purposes. It is essentially a tracking function. Concern was expressed as to why medical supplies must meet the dispensing requirements for a prescription item, when other non-pharmacy entities aren't required to meet the same restrictions. It was also questioned as to the board's enforcement discretion when there doesn't appear to be a patient harm issue. However, it was noted that some entities make a business decision to obtain a pharmacy permit and therefore, must meet more stringent requirements.

The Enforcement Committee agreed to evaluate this issue and acknowledge that like other aspects of pharmacy law, the board has discretion on how it enforces the law depending on the potential for patient harm.

Letter from CMA Regarding Internet Pharmacies

The Committee shared a letter the board received from the California Medical Association (CMA) congratulating the Medical Board of California and the Board of Pharmacy in its continued efforts in monitoring illegal prescription drugs via the Internet pharmacies, reflected in the number of actions by both boards against physicians and pharmacists for improper prescribing and dispensing.

Compounding Issues – Labels and Central Fill

The Enforcement Committee received a request from the compounding pharmacists of the California Pharmacists Association (CPhA) to discuss two issues. The first issue involved the appropriate content label of compounded products. While the current label requirements reflect information that is needed by consumers when they receive compounded products, the problem arises when the compounded product is provide in multiple units of a dosage form for which individual product labels are either not feasible, cost prohibitive or a hindrance to treatment.

CPhA surveyed some pharmacists, and it was their opinion that it should be left to the individual judgment of the compounding pharmacist as to what should be included on individual units of compounded products. In many cases, individual doses should contain some sort of label to indicate active ingredients. It was explained that the form of the label will vary depending on the dispensing unit and available space. In other cases, it was their opinion that a label on individual doses would result in little or no benefit and will cause more problems than it solves. In the case of compounded tablets and capsules, identification of any kind on individual doses isn't practical. However, in any case, the patient should be made aware of the situation and advised to always keep the doses in the box, bag or container in which it was dispensed and which it is labeled with the information that may be needed by a family member or emergency personnel in the even of a problem.

It was requested that the existing law be clarified and a dialog initiated to reach a reasonable and agreeable guideline for labels on compounded products. The Enforcement Committee responded that an ad hoc committee is going to be formed with the Department of Health Services to address issues of compounding. The committee will begin meeting next year. It was suggested that the compounding pharmacists CPhA draft guidelines for discussion with the ad hoc committee.

The second issue that was discussed was compounding in central fill pharmacies. It was explained that many pharmacists and pharmacies specialize in compounded products. For a large number of these compounded products, similar systems and facilities are needed to assure consistency in preparation and potency. Pharmacies that specialize in this practice have invested

in those systems and facilities and the products that are compounded are accepted as effective and safe.

Compounding pharmacists want to increase the access to compounded products by allowing compounding pharmacies to act as central fill pharmacies in the same way as is allowed for other prescriptions under CCR, title 16, section 1707.4. Moreover, a similar activity is currently allowed for paternal products pursuant to Business and Professions Code section 4123. The compounding pharmacists requested that the Board of Pharmacy move forward on this proposal to allow central compounding pursuant to 1707.4.

There was discussion that this issue should also be referred to the ad hoc committee on compounding and it was questioned whether this proposal could be adopted through regulation or would require legislation. The Enforcement Committee advised the proponents that it would place this issue on the October board agenda should they decide to present a legislative proposal for the board's consideration.

Adjournment

Committee Chair John Jones adjourned the meeting at 12:30 p.m.

Attachment H

California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Enforcement Team Meeting
September 17, 2003
2:00 p.m. – 3:30 p.m.

Present: Committee Chair and Board Member John Jones
Board Member Stan Goldenberg
Executive Staff
Supervising Inspectors
Inspectors
Enforcement Staff

Announcements/Introductions

Committee Chair John Jones called the meeting to order at 2:00 p.m.

Quality Improvement Efforts

Supervising Inspector Judi Nurse reported that 402 routine inspections have been performed since July 1, 2003, which resulted in 89 corrections and 34 investigations. Since the program's inception in July 2001, the total number of inspections is 5,272. This includes the inspection of over 650 probation and PRP participants.

Enforcement Analyst Cassandra Kearney reported on the consumer satisfaction survey. It was reported that 56 customer surveys were sent and 17 were returned. The average response rate to the board's performance was 2.1. Thirteen telephone surveys were made with a response rate was 2.9. (On a scale of 1-5, with 5 being the highest rating.)

The supervising inspectors reported on the many significant inspector accomplishments since the last meeting. They again acknowledged the inspectors for their extraordinary efforts to implement the compounding pharmacy licensure and inspection program.

Supervising Inspector Robert Ratcliff reported on the status of completed cases since the last team meeting. He displayed the workload for each team and their significant progress. There are 885 pending complaints/investigations. Of these, 458 reports have been submitted and 427 cases are assigned for mediation or investigation. Supervising Inspector Ratcliff acknowledged efforts to complete cases that were over the targeted time frames for closure.

Discussion of Enforcement Committee Meeting

The Enforcement Team discussed the agenda items from the Enforcement Committee meeting.

Adjournment

Committee Chair John Jones adjourned the meeting at 3:30 p.m.

Attachment I

Board of Pharmacy Enforcement Statistics
Fiscal Year 2003/2004

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 03/04
Complaints/Investigations					
Initiated	372	68			
Closed	430	97			
Pending (at the end of quarter)	935	763			763
Cases Assigned & Pending (by Team) as reported July 2, 2003					
Compliance Team	89				
Drug Diversion/Fraud	67				
Mediation Team	71				
Probation/PRP	45				
Enforcement	194				
Site Inspections					
Performed	531	51			582
Corrections Ordered	255	17			272
Application Investigations					
Initiated	82	9			91
Closed					
Approved	122	5			127
Denied	5	2			7
Total*	139	7			
Pending (at the end of quarter)	73	156			156
Citation & Fine					
Issued	359	124			483
Abated	231	11			242
Total Fines Collected	$93,425.00	$49,875.00			$143,300.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2003/2004

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 03/04
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	50	1			
Pleadings Filed	24	1			
Pending					
Pre-accusation	85	88			
Post Accusation	67	66			
Total	153	155			
Closed**	26	3			
Revocation					
Pharmacist	3				
Pharmacy	2				
Other	4				
Revocation,stayed; suspension/probation					
Pharmacist	1				
Pharmacy					
Other					
Revocation,stayed; probation					
Pharmacist	4				
Pharmacy					
Other		1			
Suspension, stayed; probation					
Pharmacist					
Pharmacy					
Other					
Surrender/Voluntary Surrender					
Pharmacist	2				
Pharmacy					
Other	2				
Public Reproval/Reprimand					
Pharmacist					
Pharmacy					
Other					
Cost Recovery Requested	$42,992.25	$7,297.50			
Cost Recovery Collected	$36,714.86	$19,206.98			

* This figure includes Citation Appeals

Board of Pharmacy Enforcement Statistics
Fiscal Year 2003/2004

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 03/04

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2003/2004

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 03/04
Probation Statistics					
Licenses on Probation					
Pharmacist	129	129			
Pharmacy	21	21			
Other	22	24			
Probation Office Conferences	8	8			
Probation Site Inspections	35	35			
Probationers Referred to AG for non-compliance	3	0			3

As part of probation monitoring, the board requires licensees to appear before the lead inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of June 30, 2003)

Program Statistics					
In lieu of discipline	0	1	0	0	1
In addition to probation	1	3	1	5	10
Closed, successful	3	0	3	3	9
Closed, non-compliant	2	3	5	4	10
Closed, other	0	0	1	0	1
Total Board mandated Participants	50	50	49	50	50
Total Self-Referred Participants*	15	15	15	15	15
PRP Site Inspections**	29	1	6	8	44
Treatment Contracts Reviewed	31	37	26	23	26

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, enforcement coordinator and lead inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

**Some PRP Participant Inspections are included in the Probation Site Inspections total.

As of October 21, 2003.

Citation and Fine Committee Statistics for July 1, 2003 – September 30, 2003

Total cases reviewed by Citation and Fine Committee	Citations Issued with fines	Citations without fines
150	218	72

Subjects referred to:			Subjects closed no further action
AG	Add. Invest.	Add. Insp.	
14	3		42

Average number of days for investigation process

Case open to citation issued	Request to Office Conference	Appeal request to hearing date
228 days	60 days	Data not available

Contested Citations Office Conference

Requested	Scheduled	Appeared	Affirmed	Amended	Dismissed	Withdrawn
38	29	11	2	4	5	0

- Total amount of citations issued this quarter $ 198, 150.00

- The committee held six meetings.

Contested Citation Appeals

Received	Sent to AG	Heard
Data not available		

Citation Breakdown by license type

RPH with fine	RPH no fine	RPH closed	PHY with fine	PHY no fine	PHY closed	PIC with fine	PIC no fine	PIC closed
74	3	17	72	60	16	72	5	18

Top Ten Violations by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	46	1716 - Variation from prescription	44	1714(d) – Operational standards and security	25
1716/1761 - Variation from Rx / Erroneous Rx	12	4125/1711 - Quality assurance program	12	1715 - Self-assessment of a pharmacy by PIC	15
4076/1716 – labeling req. / Variation from Rx	10	1714 (b) – Operational standards & security	8	4125/1711 - Quality assurance program	10
4125/1711 - Quality assurance program	8	1716/1761 - Variation from Rx / Erroneous Rx	6	4059 - Furnishing dangerous drugs without Rx	10
4063 – Rx refill prescriber authorization	6	4076/1716 – labeling req. / Variation from Rx	6	1707.2 – Duty to consult	10
1707.2 – Duty to consult	5	1715 – PHY operation in absence of pharmacist	4	4076/1716 – labeling req. / Variation from Rx	5
1714 (d) - Operational standards & security	3	1707.2 – Duty to consult	4	4063 – Rx refill prescriber authorization	5
4081 – Records of dangerous drugs	2	4063 – Rx refill prescriber authorization	4	1707.1a1c - Duty to maintain medication profiles	5
4075 - Identity req. oral / electronic Rx	1	4081 – Records of dangerous drugs	2	1761- Erroneous or uncertain prescriptions	5
4081 – Records of dangerous drugs	1	4059 - Furnishing dangerous drugs without Rx	1	1716 - Variation from prescription	5

Revision date 9/9/03

Attachment J

Attachment J will be available at the board meeting.